

Timothy B McKinney, MD

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC.	:
PELVIC REPAIR SYSTEM	:
PRODUCTS LIABILITY	: Master File No.
LITIGATION	: 2:12-MD-02327
	: MDL No. 2327
	:
	: JOSEPH R. GOODWIN
THIS DOCUMENT RELATES	: U.S. DISTRICT JUDGE
TO ALL CASES	:

- - -

June 29, 2016

- - -

Deposition of TIMOTHY B. McKINNEY, M.D.,
taken at the Hilton Garden Inn, 1885 Route 70 W.,
Lakewood, New Jersey, commencing at 9:11 a.m., on
the above date, before CONSTANCE E. PERKS, CRR,
CLR, CRC, RSA, a Federally-Approved Certified
Court Reporter and Notary Public.

- - -

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<p>1 APPEARANCES: 2 MOTLEY RICE, LLC 3 BY: JONATHAN D. ORENT, ESQUIRE 4 321 South Main Street 5 Providence, Rhode Island 02903 6 401.457.770 7 jorent@motleyrice.com 8 Counsel for the Plaintiffs</p> <p>9 TUCKER ELLIS, LLP 10 BY: MATTHEW P. MORIARTY, ESQUIRE 11 950 Main Avenue 12 Suite 1100 13 Cleveland, Ohio 44113 14 216.696.2276 15 matthew.moriarty@tuckerellis.com</p> <p>16 -and -</p> <p>17 RIKER DANZIG SCHERER HYLAND & 18 PERRETTI, LLP 19 BY: DIANA KATZ GERSTEL, ESQUIRE 20 Headquarters Plaza 21 One Speedwell Avenue 22 Morristown, New Jersey 07962-1981 23 973.451.8468 24 dgerstel@riker.com Counsel for the Defendants</p> <p>25 - - -</p>	<p>1 DEPOSITION SUPPORT INDEX</p> <p>2</p> <p>3 Direction to Witness Not To Answer Page Line Page Line (None)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8 Request For Production of Documents Page Line Page Line (None)</p> <p>9</p> <p>10</p> <p>11</p> <p>12 Stipulations Page Line Page Line (None)</p> <p>13</p> <p>14</p> <p>15</p> <p>16 Questions Marked Page Line Page Line (None)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21 - - -</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 - - -</p> <p>2 I N D E X</p> <p>3 WITNESS: TIMOTHY B. McKINNEY, M.D.</p> <p>4 EXAMINATION PAGE</p> <p>5 BY MR. ORENT 5</p> <p>6 BY MS. GERSTEL 132</p> <p>7 BY MR. ORENT 165</p> <p>8</p> <p>9 - - -</p> <p>10 E X H I B I T S</p> <p>11 NO. DESCRIPTION PAGE</p> <p>12 1 Notice to Take Deposition 7 of Dr. Timothy McKinney</p> <p>13</p> <p>14 2 Curriculum Vitae of 7 Timothy Brian McKinney, M.D.</p> <p>15</p> <p>16 3 AUGS Position Statement 61</p> <p>17</p> <p>18 4 PelvicHealthSurgery.com 105 Clinical Research webpage printout</p> <p>19</p> <p>20 - - -</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 - - -</p> <p>2 TIMOTHY B. McKINNEY, M.D.,</p> <p>3 after having been duly sworn, was</p> <p>4 examined and testified as follows:</p> <p>5 - - -</p> <p>6 EXAMINATION</p> <p>7 - - -</p> <p>8 BY MR. ORENT:</p> <p>9 Q. Good morning, Doctor. How</p> <p>10 are you this morning?</p> <p>11 A. Fine.</p> <p>12 Q. My name is Jonathan Orent</p> <p>13 and I represent the plaintiffs in this</p> <p>14 matter, and I'm going to be asking you</p> <p>15 some questions today.</p> <p>16 First of all, you've been</p> <p>17 deposed before; is that correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Approximately, on how many</p> <p>20 occasions have you been deposed?</p> <p>21 A. Probably around a dozen.</p> <p>22 Maybe a little less.</p> <p>23 Q. Okay. And so you know the</p> <p>24 rules of deposition, correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. And just to refresh your</p> <p>3 recollection, if at any time you do</p> <p>4 not hear me or do not understand a</p> <p>5 question, will you agree to ask me to</p> <p>6 repeat or rephrase the question?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And likewise, if you</p> <p>9 do answer a question, is it fair for me</p> <p>10 to conclude that you understood the</p> <p>11 question that was asked of you?</p> <p>12 A. Yes.</p> <p>13 Q. And you're doing a great job</p> <p>14 so far, but just to remind you to answer</p> <p>15 with a yes or no, rather than a nod or</p> <p>16 shake of the head. Fair enough?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. If you need a break</p> <p>19 at any time, just let me know and I'm</p> <p>20 happy to accommodate you. Okay? If</p> <p>21 there is a pending question, I would just</p> <p>22 ask that you answer the pending question</p> <p>23 and we can accommodate your break. Is</p> <p>24 that fair?</p>	<p>1 produce a set of documents. Did you</p> <p>2 bring any documents with you?</p> <p>3 A. Yes.</p> <p>4 MR. MORIARTY: That thumb</p> <p>5 drive has reliance materials for</p> <p>6 TVT General and for Maxwell.</p> <p>7 MR. ORENT: Okay. TVT</p> <p>8 General or -- or Gynemesh General?</p> <p>9 MR. MORIARTY: TVT General.</p> <p>10 That's what we're here to talk</p> <p>11 about. He was deposed on Gynemesh</p> <p>12 PS in Wave 1 for about three hours</p> <p>13 from a gentleman from Colorado.</p> <p>14 MR. ORENT: And could we go</p> <p>15 off the record for just one</p> <p>16 moment?</p> <p>17 MR. MORIARTY: Sure.</p> <p>18 (Discussion off the</p> <p>19 stenographic record.)</p> <p>20 (Deposition recessed from</p> <p>21 9:14 a.m. until 11:40 a.m.)</p> <p>22 BY MR. ORENT:</p> <p>23 Q. Good morning again, Doctor.</p> <p>24 You're here now on your General TVT</p>
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<p>1 A. Yes.</p> <p>2 Q. And Doctor, would you just</p> <p>3 state your full name for the record.</p> <p>4 A. Timothy Brian McKinney.</p> <p>5 Q. Okay.</p> <p>6 - - -</p> <p>7 (Notice to Take Deposition</p> <p>8 of Dr. Timothy McKinney, marked</p> <p>9 for identification as Exhibit No.</p> <p>10 1.)</p> <p>11 - - -</p> <p>12 (Curriculum Vitae of Timothy</p> <p>13 Brian McKinney, M.D., marked for</p> <p>14 identification as Exhibit No. 2.)</p> <p>15</p> <p>16 BY MR. ORENT:</p> <p>17 Q. Now, Dr. McKinney, I've</p> <p>18 handed you what's been marked as Exhibit</p> <p>19 1 to today's deposition, which is a copy</p> <p>20 of the Notice of Deposition for today.</p> <p>21 Have you seen this document before?</p> <p>22 A. Yes, I have.</p> <p>23 Q. Okay. And if you look,</p> <p>24 starting at page 4, there are requests to</p>	<p>1 report, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And we've previously</p> <p>4 marked as Exhibit A a copy of your -- the</p> <p>5 Notice of Deposition today and as --</p> <p>6 excuse me, as Exhibit 1 a notice of your</p> <p>7 deposition and as Exhibit 2, I believe,</p> <p>8 is a copy of your CV; is that correct?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And you have a copy</p> <p>11 of your General TVT report in front of</p> <p>12 you, as well?</p> <p>13 A. I do.</p> <p>14 Q. Now, Doctor, in your report,</p> <p>15 you note that you have a long history of</p> <p>16 using the TVT; is that correct?</p> <p>17 A. Yes.</p> <p>18 Q. You started using the TVT in</p> <p>19 what year?</p> <p>20 A. First year it was able to be</p> <p>21 done. I believe that was in '98.</p> <p>22 Q. Okay. And you subsequently</p> <p>23 published in 1999. You worked on the --</p> <p>24 the Ulmsten article; is that right?</p>

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<p>1 A. I worked on a -- the first 2 North American exposure experiences with 3 TVT. 4 Q. And Doctor, you used the TVT 5 device before there was established data 6 on its long-term safety; true? 7 A. I was in the first wave of 8 people using it. 9 Q. And Doctor, when you first 10 started using the TVT, did you tell your 11 patients that there was no long-term data 12 on the device? 13 A. Discussed with them a lot of 14 the -- the preliminary data and where it 15 was going. 16 Q. In 1998, where was the data 17 going? 18 A. It had seemed that on 19 short-term data that it was very 20 efficacious and minimally invasive and 21 was at least as good as the results that 22 had been coming out. And the whole 23 reason why I ended up getting into this 24 field was because there was so little</p>	<p>1 correct? 2 A. There was no long-term data 3 for too many procedures that were out 4 there being done for incontinence. 5 That's why I brought up that aspect. But 6 I had been -- the Integral Theory had 7 been looked at. I had been privy to be 8 able to talk to Ulmsten privately as well 9 as personally for several reasons. One 10 was that I utilized him for helping me 11 develop my urodynamic pressure catheter 12 back in the middle '90s, and so I got to 13 be in his lab and see exactly what went 14 on within -- with the development of this 15 project. 16 Q. But again, in 1998, did 17 you tell your patients that you didn't 18 know what the long-term impact of having 19 polypropylene mesh in the vagina 20 was? 21 A. By that time, there would 22 have been a number of uses of 23 polypropylene, as well as other graft 24 materials through the years for use for</p>
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<p>1 evidence-based medicine that was out 2 there. 3 Bergman in 1995 was the 4 first person to ever publish any kind of 5 prospective randomized trials looking at 6 incontinence procedures, and there were 7 about 160 procedures at the time, but his 8 five-year data in 1995 on the anterior 9 Kelly plication, the Raz/Stamey Pereya 10 type of urethropexy and then the Burch, 11 that data came out and was rather 12 surprising to the world that -- the 13 standard of care at the time for 14 incontinence was Kelly plication, which 15 had a -- about a 37 percent five-year 16 success rate of not leaking and -- 17 Q. If I might just cut you off, 18 Doctor -- 19 A. -- a 42 -- 20 Q. -- my question was 21 relative to the data on the TVT, itself. 22 You would agree that there was no 23 long-term data at the time that you 24 implant -- that you started using it,</p>	<p>1 reconstruction, as well as incontinence, 2 had been exposed to in my clinical 3 training. My offspring was -- had been 4 -- or I was trained by -- trained by 5 Ostergard who is a huge Gore-Tex person. 6 There was a lot of Mersilenes. There 7 were a lot of looking to see what would 8 be the better of materials that were out 9 there, and it became obvious that the 10 polypropylene, at least, was an inert 11 and -- and a better material than some of 12 the other woven materials that were given 13 or the Gore-Tex, which was rather 14 caustic. 15 Q. Well, I want to just focus 16 on the question that I asked you, Doctor. 17 And with regard to the TVT device, 18 when you started using it, did you 19 tell patients, specific to that 20 device, that you did not know what the 21 long-term safety or efficacy was? 22 A. For polypropylene? It had 23 been used for years and years and years. 24 I had been utilizing it for hernia</p>

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<p>1 repairs. So it's been -- it had been in 2 my hands and used with a comfort level 3 for more than probably -- may -- maybe 4 some of my other people that may have 5 started using it, but from my hands I had 6 been with prop -- polypropylene for years 7 and years. 8 Q. I understand that that's 9 your position, but my question was 10 specific to the TVT. Did you tell your 11 patients that you did not know what the 12 long-term outcomes in terms of safety or 13 efficacy were with regard to the TVT 14 device when you started using it in 1998? 15 A. I looked at the initial data 16 that came out from Ulmsten's group and it 17 had very little in the line of 18 complications in comparison to the vertex 19 pubic urethral -- 20 Q. Doctor, that's not an answer 21 to my question, and I'm going to move to 22 strike that prior answer. 23 Doctor, my question was: 24 Did you tell your patients, yes or no,</p>	<p>1 THE WITNESS: I didn't talk 2 to them about the long-term 3 efficacy of the procedure. 4 BY MR. ORENT: 5 Q. And there was no long-term 6 data on the procedure, correct? 7 A. There was short-term data. 8 Q. And did you tell them that 9 there was no long-term data on the 10 efficacy of the procedure? 11 MS. GERSTEL: Objection; 12 asked and answered. 13 THE WITNESS: I'm not sure 14 whether I really understood any 15 major efficacy problems, so no. 16 BY MR. ORENT: 17 Q. And did you tell them about 18 the potential for long-term complications 19 or long-term de novo complications 20 following the procedure? 21 A. I talked to -- 22 MS. GERSTEL: Objection; 23 asked and answered. 24 THE WITNESS: I talked to</p>
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<p>1 that you did not know what the long-term 2 safety or efficacy was related to the TVT 3 in 1998? 4 A. I had told them that this 5 was a new procedure that was being looked 6 at as being at least as good as a more 7 invasive procedure and that there were -- 8 the results were utilizing a Prolene 9 permanent hernia mesh type of material, 10 which was a Type I large pore material, 11 and that it had been -- multiple other 12 materials had been looked at by this same 13 group to finally formulate which material 14 they felt was going to be less 15 problematic. So -- 16 Q. All right. Doctor, I'm 17 going to cut you off, because, again, 18 that's not an answer to my question. 19 My question was: Did you 20 tell your patients in 1998 that you did 21 not know the long-term safety or efficacy 22 of the TVT device? 23 MS. GERSTEL: I'm going to 24 object. Asked and answered.</p>	<p>1 them about all the complications 2 of any of my surgical procedures 3 for incontinence, which had the 4 whole litany of complications 5 which included recurrence, suture 6 or damage to bowel, bladder, 7 ureters, erosion of the materials 8 that I utilized into the urethra 9 or -- or bladder or both and -- 10 BY MR. ORENT: 11 Q. Did you tell the patients 12 that you did not know the complication 13 rates? 14 A. Not on the specifics on -- 15 with the -- the one centimeter thick -- 16 wide mesh material, but -- 17 Q. Did you tell the patients in 18 1998 that there was no data yet 19 establishing what the long-term 20 complication rates were for this device? 21 A. There were -- 22 MS. GERSTEL: Objection; 23 asked and answered. 24 THE WITNESS: There were</p>

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<p>1 short-term complications rates 2 were -- which were very minimal. 3 BY MR. ORENT: 4 Q. Did you tell them that it 5 was unknown what the long-term 6 complication rates were? 7 MS. GERSTEL: Objection; 8 asked and answered. To the extent 9 you're looking for a yes or no 10 answer, he's already answered the 11 question. 12 BY MR. ORENT: 13 Q. Go ahead. 14 A. No. 15 Q. And Doctor, you would agree 16 with me that in the most recent 17-year 17 study, in fact, between years 11 and 17, 18 the two most recent Nilsson studies, new 19 complications were actually found, 20 correct? There was new erosion between 21 year 11 and 17? 22 MS. GERSTEL: Object to 23 form. 24 THE WITNESS: It was more of</p>	<p>1 Q. Do you agree, yes or no, did 2 it appear on the data tables in the year 3 11 study versus the year 17 study where 4 it did appear? 5 MS. GERSTEL: Objection -- 6 THE WITNESS: I think -- 7 MS. GERSTEL: -- he's 8 already answered. 9 THE WITNESS: -- then, 10 again, it was -- the data was all 11 within the one definition, and it 12 became a secondary additional 13 split of the -- the data. 14 BY MR. ORENT: 15 Q. Doctor, did you have any 16 work relative to participating in that 17 17-year study? 18 A. I did not. 19 Q. So this is your 20 interpretation of the two studies, 21 correct? 22 A. That is correct. 23 Q. You have no independent 24 knowledge, correct?</p>
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<p>1 a definition that was splitting 2 hairs to try to determine or -- a 3 better way to look at the 4 different ways of expressing; was 5 it an erosion, was it an exposure, 6 did the skin break down, did it 7 actually erode into a structure? 8 So there were -- there was more of 9 a -- an expansion of the one term 10 that we used -- 11 BY MR. ORENT: 12 Q. Well, you would agree 13 that -- 14 A. -- which was erosion. 15 Q. You would agree that there 16 was a new reported complication? 17 A. It wasn't a new reported 18 complication; it was an expansion of 19 the -- the old definition and divided 20 into two different categories. 21 Q. Well, it previously didn't 22 appear in the data tables, correct? 23 A. It was a -- under a 24 comprehensive title.</p>	<p>1 A. Other than what I've read. 2 Q. What have you read? 3 A. Just the paper. 4 Q. Okay. So what I'm saying 5 is, aside from the studies, themselves, 6 you have no other knowledge that informs 7 you on these two studies? 8 A. That is correct. 9 Q. Okay. In your report, 10 Doctor, is it fair to say that you do not 11 rely upon any of the internal documents 12 of Ethicon to determine what Ethicon knew 13 at any point in time? 14 MS. GERSTEL: Object to the 15 form. 16 THE WITNESS: I'm a little 17 confused on that, but in the time 18 of 1998 -- 19 BY MR. ORENT: 20 Q. No. What I'm asking 21 is: Just generally speaking, Doctor, 22 as you sit here today, do you have 23 any opinions relative to what Ethicon 24 knew at any particular point in</p>

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<p>1 time relative to mesh and mesh 2 complications? 3 MS. GERSTEL: Object to the 4 form. 5 THE WITNESS: Do I have a -- 6 BY MR. ORENT: 7 Q. So, Doctor, let me ask it a 8 different way. You don't cite in your 9 primary report on TVT any internal 10 corporate documents, correct? 11 A. That is correct. 12 Q. And Doctor, is it fair to 13 say that you will not be offering any 14 opinions as to the state of the corporate 15 knowledge inside Ethicon at any point in 16 time? 17 MS. GERSTEL: Object to the 18 form. 19 THE WITNESS: I mean, I've 20 read a lot of the internal 21 documents. I didn't find it 22 necessary to end up putting it in 23 in my defense of the actual 24 procedure, itself --</p>	<p>1 form. 2 BY MR. ORENT: 3 Q. So now, Doctor, are you 4 intending on testifying on any opinions 5 that you have formed based on the 6 corporate documents that you have 7 reviewed? 8 A. Not in this. 9 Q. So, fair to say that you 10 will not be offering any opinions on 11 corporate knowledge of Ethicon at 12 trial in this case? 13 MS. GERSTEL: Object to the 14 form. 15 THE WITNESS: I'm not going 16 to be... I mean, as it pertains 17 to my other opinions that I have 18 about the -- the company's 19 participation and what they tried 20 to do to end up bringing the best 21 products to market and all the 22 work that they went through to try 23 to end up seeing the best product 24 make it to market, I think that's</p>
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<p>1 BY MR. ORENT: 2 Q. Well -- 3 A. -- as it is the gold 4 standard. It has definitely a much 5 stronger efficacy and safety profile than 6 the existing procedures that are out 7 there for incontinence and -- 8 Q. Again, Doctor, I just -- 9 we're under a limited time and so -- 10 A. Yes. 11 Q. I'm only allowed to ask you 12 two hours worth of questions. 13 A. Correct. 14 Q. You tend to be -- I know 15 you're trying to be helpful, but if you 16 could just focus on the question that I'm 17 asking. They're very precise questions, 18 and if you could focus on them, it would 19 allow us to get through much more 20 material in the short period of time and 21 prevent me from having to go to the court 22 or ask defense counsel for an extension 23 over the two hours. Okay? 24 MS. GERSTEL: Object to the</p>	<p>1 part of my ability. But if you're 2 trying to say am I going to 3 comment on all the internal 4 makings of the company, I think 5 the company would be better off 6 saying something about it. 7 BY MR. ORENT: 8 Q. And you don't cite any 9 documents, corporate documents, in 10 this report, correct? 11 A. That's correct. 12 Q. Now, Doctor, how long did 13 you spend in drafting this particular 14 report? 15 A. A lot of time. 16 Q. And what's that, 100 hours, 17 200 hours? 18 A. No. I don't know. Probably 19 less than 50. 20 Q. Okay. And in that time, how 21 much of that time of that less than 50 22 hours was spent -- do you think it's 23 closer to 40 or 50? 24 A. 50.</p>

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<p>1 Q. In approximately 50 hours of</p> <p>2 time -- first of all, have you billed</p> <p>3 Ethicon yet?</p> <p>4 A. I have not.</p> <p>5 Q. Have -- how much of that</p> <p>6 time was spent reviewing literature?</p> <p>7 A. It was kind of interspersed</p> <p>8 in there, but a good amount of -- over</p> <p>9 half.</p> <p>10 Q. Okay. And how much time was</p> <p>11 spent reviewing corporate documents?</p> <p>12 A. It was more earmarked</p> <p>13 towards the things that I thought were</p> <p>14 important within the documents that I'd</p> <p>15 need to know.</p> <p>16 Q. Fair to say that you spent</p> <p>17 minimal time looking at corporate</p> <p>18 documents?</p> <p>19 MS. GERSTEL: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: I still spent</p> <p>22 time in there, yes.</p> <p>23 BY MR. ORENT:</p> <p>24 Q. But you would agree that</p>	<p>1 any of the material that counsel pointed</p> <p>2 out to you?</p> <p>3 A. Am I relying on it to --</p> <p>4 Q. Support your opinions.</p> <p>5 A. -- make my opinion?</p> <p>6 Q. Yes.</p> <p>7 A. Other than that I thought</p> <p>8 that they've done a banner job of putting</p> <p>9 their product together.</p> <p>10 Q. Well, I guess -- I'm</p> <p>11 entitled to ask you questions on what</p> <p>12 you're going to be offering at trial.</p> <p>13 Are you going to be talking about</p> <p>14 emails at trial?</p> <p>15 MS. GERSTEL: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Only if really</p> <p>18 pushed into it.</p> <p>19 BY MR. ORENT:</p> <p>20 Q. So as you sit here, you</p> <p>21 don't intend on doing it, correct?</p> <p>22 A. I don't intend to unless</p> <p>23 I'm --</p> <p>24 Q. Okay.</p>
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<p>1 that would be minimal time?</p> <p>2 A. It was --</p> <p>3 MS. GERSTEL: Objection.</p> <p>4 THE WITNESS: -- less time</p> <p>5 than some other aspects to it, but</p> <p>6 yes, there were time spent, IFUs</p> <p>7 and other --</p> <p>8 BY MR. ORENT:</p> <p>9 Q. And you're making a very</p> <p>10 valid distinction. I'm not including</p> <p>11 IFUs in what I call corporate</p> <p>12 documents. I think that those are</p> <p>13 discussed in your report. So --</p> <p>14 A. You mean looking at emails</p> <p>15 and all the little nuances --</p> <p>16 Q. I'm looking at -- talking</p> <p>17 about emails and PowerPoints and some of</p> <p>18 the other documents that are listed</p> <p>19 as reliance material in some of your</p> <p>20 reports.</p> <p>21 A. I looked through some of</p> <p>22 them in cursory and what counsel pointed</p> <p>23 out to me as well.</p> <p>24 Q. Okay. Are you relying upon</p>	<p>1 A. -- pushed.</p> <p>2 Q. The only Ethicon written</p> <p>3 documents that you intend on relying</p> <p>4 upon are the instructions for</p> <p>5 use?</p> <p>6 A. That would be a --</p> <p>7 MS. GERSTEL: Objection.</p> <p>8 THE WITNESS: -- a high</p> <p>9 probability.</p> <p>10 BY MR. ORENT:</p> <p>11 Q. Okay. Now, we can both</p> <p>12 agree you're not a regulatory expert,</p> <p>13 correct?</p> <p>14 A. I am not, but I do have</p> <p>15 experience with that because of my</p> <p>16 company creating IFUs, creating CRs.</p> <p>17 Unfortunately, it's a part of business.</p> <p>18 Q. Okay. Are you going to be</p> <p>19 offering opinions relative to the 510(k)</p> <p>20 process versus a premarket approval?</p> <p>21 A. Not heavily, no.</p> <p>22 Q. Okay. You're aware that</p> <p>23 there is a difference, correct?</p> <p>24 A. Yes.</p>

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<p>1 Q. And you're aware that mesh 2 is 510(k), correct? 3 A. That is correct. 4 Q. And mesh does not have the 5 TVT, TVT-O, or other mesh devices do not 6 have FDA approval, correct? 7 MS. GERSTEL: Object to 8 form. 9 THE WITNESS: They've gone 10 through scrutiny from the FDA, and 11 so they have -- have obviously 12 looked at them well enough to give 13 their okay. 14 BY MR. ORENT: 15 Q. Well, you're aware that the 16 510(k) process that these devices went 17 through is not a -- does not evaluate the 18 safety or efficacy of the device, 19 correct? 20 MS. GERSTEL: Object to 21 form. 22 THE WITNESS: Well, they've 23 gone back and are asking for more 24 data, although the company has</p>	<p>1 Q. You're not a biomedical 2 engineer, correct? 3 A. That is correct. 4 Q. You're not an expert in 5 material science, correct? 6 A. Correct. 7 Q. You're not an expert in the 8 design of meshes, correct? 9 A. Correct. 10 Q. You're not a labeling 11 expert, correct? 12 A. Correct. 13 Q. And you're not a warnings 14 expert, correct? 15 A. Correct. 16 Q. You discussed pore size to 17 some degree in your report. Are you an 18 expert on what the ideal pore size is for 19 transvaginally-placed midurethral slings? 20 A. Just from papers that I've 21 read. The Ahmed report was probably one 22 of the first ones that really looked over 23 and quantitated and -- and discussed the 24 different categories for what meshes were</p>
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<p>1 produced a lot of data to the FDA 2 in response to the cytotoxicity -- 3 BY MR. ORENT: 4 Q. Right. Right. But, again, 5 my -- 6 A. -- and efficacy of the -- 7 Q. My question's about the 8 process and the initial process. You're 9 aware that 510(k) as a process does not 10 evaluate the safety and efficacy of a 11 device, it compares it to a predicate 12 device, correct? 13 MS. GERSTEL: Objection. 14 THE WITNESS: SME, too. 15 BY MR. ORENT: 16 Q. And the premarket approval 17 process or the PMA process looks at 18 safety and efficacy of devices and 19 results in approval, correct? 20 A. Yes, sir. 21 Q. Okay. Now, Doctor, 22 you're not a pathologist, 23 correct? 24 A. That is correct.</p>	<p>1 and was really driven towards the -- the 2 Type I mesh being better versus a 3 Gore-Tex. We kind of got it by trial and 4 error, unfortunately, because a lot of 5 docs like Ostergard had put in tons of 6 them and taught us to put in other graft 7 materials and Mersilene and -- 8 Q. You would agree, though, 9 Ahmed -- Ahmed -- you're referring to 10 the 1997 Ahmed, right? 11 A. Yes. 12 Q. And you would agree that 13 that was in relationship to hernia mesh, 14 correct? 15 A. It was. 16 Q. Okay. And in terms of 17 vaginal mesh, there's never been a 18 publication or at least pre -- strike 19 that. 20 What publications are you 21 aware of that state what the ideal pore 22 size is for vaginally-placed meshes? 23 A. The initial work was Ahmed. 24 It was basically characterizing every</p>

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<p>1 single one of the graft materials that 2 are out there. I think I -- something 3 that I looked at, the vaginal -- I think 4 I talked a little bit more about like a 5 Falconer study, which had looked at TVT 6 materials, itself, in relationship to 7 other reactive tissues -- 8 Q. Would -- 9 A. -- including cadaveric 10 fascia, and that TVT material was more 11 elastic and better suited for vaginal 12 placement. I'm -- I'm not -- I'm not the 13 -- I'm not seeing anything other than 14 Falconer's and -- 15 Q. Now, Doctor, in preparing 16 your report here, did you do a 17 literature search specific to pore 18 size to opine what the appropriate 19 pore size for a vaginal mesh should be? 20 A. I did not find anything, no. 21 Q. You did not find anything. 22 Did you actually go about and do a search 23 for material specific to vaginal mesh 24 pore size?</p>	<p>1 defining and identifying the ideal mesh 2 density as you sit here today, correct? 3 A. Correct. 4 Q. In terms of fiber diameter, 5 you agree with me, Doctor, that you are 6 not an expert on the ideal fiber diameter 7 of mesh? 8 A. I am not. 9 Q. In terms of tensilary 10 strength, would you agree with me, 11 Doctor, that you are not an ideal -- 12 excuse me, you are not a mesh expert on 13 the ideal tensilary strength of a 14 vaginally-placed mesh? 15 A. I am not. 16 Q. Okay. Elasticity, would you 17 agree with me that you are not an expert 18 on the elasticity of vaginally-placed 19 meshes? 20 A. I'm not. 21 Q. Doctor, I noticed -- aside 22 from reference going back to 1999 and the 23 first participation in the studies 24 of vaginal meshes, would agree with me,</p>
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<p>1 A. I did not. 2 Q. Okay. Would you agree with 3 me, Doctor, that you are not an expert on 4 vaginal mesh pore size? 5 MS. GERSTEL: Object to the 6 form. 7 THE WITNESS: I'm just a -- 8 familiar with the general pore 9 size for hernia mesh materials 10 utilized within the body. 11 BY MR. ORENT: 12 Q. Now, Doctor, in your 13 report, you don't state anything about 14 ideal mesh density; is that correct? 15 A. I do not. 16 Q. Okay. And would you agree 17 you're not an expert on the ideal mesh 18 density? 19 A. Right at present, I'm not 20 sure whether it exists today. We're 21 still trying to end up getting a better 22 product out there. 23 Q. But you would agree that 24 you, yourself, are not an expert on</p>	<p>1 Doctor, that you are not -- you have not 2 done an extensive history into the 3 research and the development of vaginal 4 grafts from 1920s forward? 5 MS. GERSTEL: Object to the 6 form. 7 THE WITNESS: I have read 8 over the history aspect of it. 9 I've, unfortunately, been living 10 the experimental process, I think, 11 that was going on. The way I was 12 taught is totally different from 13 what I would be doing today. I 14 hope I've been involved in 15 changing the course of history. 16 Why I went into this field, 17 because there were all kinds of 18 things being utilized because the 19 guru at the time was saying that 20 this is the way it should be done. 21 And so I was almost brought up 22 with the fact that if it was done 23 that way, it should be done that 24 way, and that was the Penn way.</p>

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<p>1 And if it was done at Mayo Clinic</p> <p>2 this way, you -- you should follow</p> <p>3 like a -- a robot. I challenged</p> <p>4 it.</p> <p>5 BY MR. ORENT:</p> <p>6 Q. Now, with regard to,</p> <p>7 though, the history and development</p> <p>8 of vaginal meshes and grafts, would</p> <p>9 you agree that you're not an expert</p> <p>10 in terms of the historical development</p> <p>11 of these devices and not going to be</p> <p>12 providing expert testimony in trial</p> <p>13 as to the historical development of</p> <p>14 devices preceding the TVT?</p> <p>15 MS. GERSTEL: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Well, I've</p> <p>18 been able to talk to Ulmsten and</p> <p>19 his partner who had extensively</p> <p>20 looked at multiple different</p> <p>21 materials that they tried for</p> <p>22 their slings and what they had</p> <p>23 determined to be inappropriate</p> <p>24 materials all the way up until</p>	<p>1 form.</p> <p>2 THE WITNESS: Other than my</p> <p>3 own personal experiences with it</p> <p>4 and all my frustrations with that,</p> <p>5 I think that's all pertinent to my</p> <p>6 expert opinion on the materials</p> <p>7 used in the development and the</p> <p>8 staging of vaginal meshes.</p> <p>9 BY MR. ORENT:</p> <p>10 Q. Well, let's look at something</p> <p>11 specific then.</p> <p>12 Are you to be offering</p> <p>13 opinions as to whether or not</p> <p>14 polypropylene -- whether bacteria can</p> <p>15 travel along polypropylene?</p> <p>16 A. Just historically, I know</p> <p>17 that it's not a higher -- it's not a high</p> <p>18 probability in comparison to woven</p> <p>19 materials, that polypropylene is less</p> <p>20 likely to end up having that occur.</p> <p>21 Q. Do you know what rates of --</p> <p>22 of -- strike that.</p> <p>23 Is there a race to the</p> <p>24 surface of bacteria? Have you heard that</p>
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<p>1 they came upon the -- the Type I</p> <p>2 Prolene, which they found was -- I</p> <p>3 think it was in 1994 was when they</p> <p>4 finally honed it in and said, This</p> <p>5 is the material that we're going</p> <p>6 to end up using because of the</p> <p>7 lesser of the -- the -- the risks</p> <p>8 than the Gore-Tex and the -- some</p> <p>9 of the other materials that were</p> <p>10 out there at the time, Mersilene</p> <p>11 and --</p> <p>12 BY MR. ORENT:</p> <p>13 Q. Now --</p> <p>14 A. -- Marlex.</p> <p>15 Q. -- are you going to be</p> <p>16 offering testimony on the historical</p> <p>17 development of meshes going back through</p> <p>18 time in terms of what was known in</p> <p>19 history in terms of erosion, when erosion</p> <p>20 was first learned of, when various</p> <p>21 informational pieces were known at</p> <p>22 various times, things that don't appear</p> <p>23 in your written report?</p> <p>24 MS. GERSTEL: Object to the</p>	<p>1 term before?</p> <p>2 A. I have not, but --</p> <p>3 Q. Fair to say that you haven't</p> <p>4 done an extensive search into the</p> <p>5 literature on bacterial wicking vis-à-vis</p> <p>6 polypropylene?</p> <p>7 A. Wicking as far as</p> <p>8 polypropylene, it's less likely than some</p> <p>9 other materials that were out there --</p> <p>10 Q. I understand that, but have</p> <p>11 you done an --</p> <p>12 A. -- that were chosen for the</p> <p>13 vaginal use.</p> <p>14 Q. Have you done an extensive</p> <p>15 literature search on that for preparation</p> <p>16 of your report?</p> <p>17 A. Not extensive.</p> <p>18 Q. Have you done any?</p> <p>19 A. Not literature search. Just</p> <p>20 in the readings of the state of materials</p> <p>21 that were out there.</p> <p>22 Q. And Doctor, in terms of</p> <p>23 degradation, you state in some opinions</p> <p>24 in your report that, I believe, you don't</p>

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<p>1 believe that you have ever seen 2 degradation. 3 Doctor, are you going to be 4 offering opinions at trial in this case 5 that degradation does not occur? 6 A. Not to a clinically-relevant 7 state at all, if any. I haven't seen it 8 in thousands of mesh implantation cases 9 through the years. I'm not seeing 10 breakdown. I'm not seeing any in really 11 the materials even that I've taken out. 12 Q. Doctor, do you know what -- 13 when I say "degradation," do you envision 14 like a physical breakdown? Is that what 15 you're envisioning? 16 A. It comes in many forms. 17 Q. Do you understand that 18 when in this litigation, generally 19 speaking, people have been referring 20 to degradation, they're referring to 21 the division of or the degrading of 22 a molecule into two separate 23 molecules -- 24 MS. GERSTEL: Objection.</p>	<p>1 if you understand that degradation just 2 is a -- so that we're on the same 3 page, is a chemical alteration of the -- 4 the molecules within the polypropylene, 5 do you have an opinion to a reasonable 6 degree of medical certainty whether or 7 not that that occurs? I'm not asking 8 about the significance. I'm asking 9 whether it occurs. 10 MS. GERSTEL: Objection. 11 THE WITNESS: It is 12 controversial in the human body. 13 BY MR. ORENT: 14 Q. And Doctor, would you -- are 15 you going to be offering -- strike that. 16 Is this outside the area of 17 your expertise, the molecular -- are you 18 going to be talking about what happens in 19 a molecular level with polypropylene? 20 A. No. 21 Q. Fair to say that you 22 might only be talking about whether or 23 not there are clinical impacts of 24 degradation?</p>
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<p>1 BY MR. ORENT: 2 Q. -- in the polypropylene 3 chain? 4 A. I -- I don't -- I don't 5 agree with that. 6 Q. You don't agree that that's 7 what we've been talking about or you 8 don't -- 9 A. Oh, no. 10 Q. -- agree that that happens? 11 A. I don't agree, and there's 12 some -- some controversy in the 13 literature over that. And if it is 14 existing, it's not showing up in a 15 clinical manifestation after -- 16 Q. All right. 17 A. -- and particularly in this 18 case on a TVT, TVO -- T-O, there's 19 millions of cases that have been done 20 over a 17-year period, and there's no 21 association with any kind of a breakdown 22 cytotoxicity or any kind of problem in 23 that way. 24 Q. Now, going back, though, so</p>	<p>1 A. That would be -- yes. 2 Q. And you're not going to be 3 talking about whether or not it happens 4 or not, but whether you see clinical 5 impacts of it; fair to say? 6 MS. GERSTEL: Objection. 7 THE WITNESS: Clinical 8 impacts, as well as whatever I've 9 read. 10 BY MR. ORENT: 11 Q. Okay. Well, have you done 12 an extensive literature search on 13 degradation and polypropylene? 14 MS. GERSTEL: Object to 15 form. 16 THE WITNESS: I've looked 17 over a number of papers. I don't 18 know whether it's a 100 percent 19 complete, but I've read a number 20 of them. 21 BY MR. ORENT: 22 Q. And Doctor, did you do 23 these searches for these papers 24 yourself?</p>

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<p>1 A. Some. Some were given to</p> <p>2 me.</p> <p>3 Q. Okay. Did you start with</p> <p>4 Anderson's papers?</p> <p>5 A. Not that far back.</p> <p>6 Q. Okay. Do you know who</p> <p>7 Anderson is?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Did you look at any</p> <p>10 of Ethicon's internal documents on</p> <p>11 degradation?</p> <p>12 A. Can't recall.</p> <p>13 Q. Would you recall if Ethicon</p> <p>14 reported internally that degradation</p> <p>15 of Prolene occurred? Would that --</p> <p>16 would you recall that if you had seen it?</p> <p>17 MS. GERSTEL: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: I can't</p> <p>20 recall.</p> <p>21 BY MR. ORENT:</p> <p>22 Q. Okay. How many -- how much</p> <p>23 time did you spend researching the issue</p> <p>24 of degradation?</p>	<p>1 you still use TVT?</p> <p>2 A. Yes.</p> <p>3 Q. And --</p> <p>4 A. Or did up until a couple</p> <p>5 months ago.</p> <p>6 Q. And that's when you took</p> <p>7 your sabbatical?</p> <p>8 A. That is correct. I may go</p> <p>9 back if I decide to go back into a</p> <p>10 private -- or a group practice where I</p> <p>11 have -- more -- more or less not have to</p> <p>12 worry about finances.</p> <p>13 Q. Now, when you started</p> <p>14 using TVT in 1998 through the present,</p> <p>15 how many TVT or TVT-O procedures have</p> <p>16 you done? Can you estimate?</p> <p>17 A. I don't know. Thousand</p> <p>18 plus.</p> <p>19 Q. Now --</p> <p>20 A. Do you -- would you consider</p> <p>21 that as in all midurethral slings?</p> <p>22 Because it's definitely thousands --</p> <p>23 Q. Okay. Did --</p> <p>24 A. -- because some hospital --</p>
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<p>1 A. It's just the papers that I</p> <p>2 was able to read and looking at some of</p> <p>3 the -- even the more recent one just came</p> <p>4 out which determined that what looks like</p> <p>5 a degradation may not be and that the</p> <p>6 protein cracking is really just protein.</p> <p>7 Once you're able to remove that, the</p> <p>8 actual fibers are intact.</p> <p>9 Q. So essentially, you remove</p> <p>10 the degradation layer, the fiber's</p> <p>11 intact?</p> <p>12 A. Correct.</p> <p>13 Q. Now, Doctor, with regard to</p> <p>14 these studies that you reference, and you</p> <p>15 reference the hundred RCTs relative to</p> <p>16 TVT, Doctor, did you perform any kind of</p> <p>17 meta-analysis on these studies?</p> <p>18 A. I did not. I relied on the</p> <p>19 meta-analysis that was done by -- by the</p> <p>20 experts out there. Cochran, I think, is</p> <p>21 the -- the -- the largest one that I saw.</p> <p>22 That was on, I think, 71 or -- studies or</p> <p>23 81 studies of about 12,000-plus patients.</p> <p>24 Q. Now, Doctor, are you -- do</p>	<p>1 I worked at four hospitals. Some</p> <p>2 hospitals only gave us the opportunity to</p> <p>3 use certain companies' products. So --</p> <p>4 Q. So fair to say --</p> <p>5 A. -- it's hard to break it</p> <p>6 down.</p> <p>7 Q. Okay. Now, with regard to</p> <p>8 the Ethicon, fair to say then that you</p> <p>9 can't give the jury a scientific analysis</p> <p>10 of your own experience relative to TVT</p> <p>11 or TVT-O only?</p> <p>12 MS. GERSTEL: Objection.</p> <p>13 BY MR. ORENT:</p> <p>14 Q. You haven't tracked the data</p> <p>15 on your patients?</p> <p>16 A. Well, within -- because I'm</p> <p>17 in a university setting, we do track</p> <p>18 our -- our -- our paper -- our patients.</p> <p>19 The residents are kind of required to do</p> <p>20 that, and I have fellows. I have three</p> <p>21 fellows in female pelvic medicine and</p> <p>22 reconstructive surgery. First fellow</p> <p>23 started with me back in 19 -- imagine</p> <p>24 this, '98. It was a non-accredited</p>

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<p>1 fellowship. I now have a credited 2 fellowship. 3 Q. So do you have a 4 compilation of all that data in terms 5 of what your own safety and long-term 6 efficacy rates are? 7 A. I have. It's more -- like 8 you said, it's over -- it does have more 9 than one procedure involved with it. 10 Q. Fair to say that any of 11 your own experiences that you'll be 12 talking about are based on your own 13 clinical impression rather than raw 14 data? 15 MS. GERSTEL: Objection. 16 THE WITNESS: It's kind of 17 both. 18 BY MR. ORENT: 19 Q. Well -- and Doctor, would it 20 be fair to say that you haven't produced 21 any data of your -- aside from your 22 published study that you participated 23 in with the first 95 patients to get 24 TVT in North America, you -- you're</p>	<p>1 THE WITNESS: I would 2 imagine there are some 3 differences. 4 BY MR. ORENT: 5 Q. Are you an expert on what 6 those differences might be? 7 A. No. 8 Q. Do you know why antioxidant 9 packages are put into polypropylene? 10 A. As far as prevention from 11 exposures. 12 Q. And Doctor, do you have 13 medical opinions or are you going to be 14 presenting any opinions on why 15 antioxidant packages are included in 16 polypropylenes? 17 MS. GERSTEL: Objection. 18 THE WITNESS: No. 19 BY MR. ORENT: 20 Q. Okay. And likewise, you're 21 not going to be presenting any opinions 22 as to why Ethicon chose the polypropylene 23 that it did or the particular type of 24 antioxidants within the Ethicon</p>
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<p>1 not going to be presenting any actual 2 data to the jury on your actual 3 experience, correct? 4 A. I will not. 5 Q. Now, Doctor, do you know to 6 a reasonable degree of medical certainty 7 whether all polypropylenes are the same? 8 MS. GERSTEL: Objection. 9 THE WITNESS: I'm not sure 10 what you mean. Polypropylene 11 meaning the way in which it's 12 created or presented as a mesh 13 material or -- 14 BY MR. ORENT: 15 Q. Right. 16 A. -- as a suture material 17 or -- 18 BY MR. ORENT: 19 Q. The substance. So is the 20 chemical that's in polypropylene in, 21 for example, a Boston Scientific product, 22 is it the same polypropylene that's in an 23 Ethicon? 24 MS. GERSTEL: Objection.</p>	<p>1 polypropylene, correct? 2 A. I am not. 3 MS. GERSTEL: Objection. 4 BY MR. ORENT: 5 Q. Doctor, do you rely on any 6 SEM imagery in forming your opinions in 7 this case? 8 (Phone interruption.) 9 MR. ORENT: We can go off 10 the record. 11 (Discussion off the record.) 12 MR. ORENT: Can you read 13 back the last question? 14 (Reporter read back from the 15 stenographic record.) 16 THE WITNESS: Can you give 17 me the -- what the SEM -- 18 BY MR. ORENT: 19 Q. Scanning electron 20 microscopy. 21 A. Electron microscope, right. 22 Not other than what's in papers. 23 Q. Are you going to be offering 24 any opinions as to whether tissue ingrows</p>

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<p>1 into fractures within the polypropylene 2 fibers, whether it's in vivo or whether 3 or not the cracks are formed after 4 excision?</p> <p>5 MS. GERSTEL: Objection.</p> <p>6 THE WITNESS: I -- I believe 7 that there's a lot of changes that 8 go on if you end up removing graft 9 material, because there's a lot of 10 trauma that can go on from trying 11 to extract these materials, and 12 then when you're ending up looking 13 at them, there are -- are 14 variations in it.</p> <p>15 So from the standpoint of a 16 generalized look at it, I'm going 17 to be commenting that there are 18 some reasons for that to be 19 cracked.</p> <p>20 BY MR. ORENT:</p> <p>21 Q. Are you --</p> <p>22 A. Am I the total expert on --</p> <p>23 on it? Probability not.</p> <p>24 Q. Now, Doctor, when you --</p>	<p>1 Q. Okay. And Doctor, would you 2 agree that the instructions for use are 3 the same for laser-cut and 4 mechanically-cut TVTs and TVT-Os?</p> <p>5 A. Yes.</p> <p>6 Q. Doctor, do you have a -- an 7 opinion -- do you know whether or not 8 there are any mechanical differences 9 between laser-cut and mechanically-cut 10 TVT and TVT-O?</p> <p>11 A. I don't have -- I don't 12 believe there is any real difference in 13 the -- the strength of the two slings.</p> <p>14 Q. Again, that's the strength. 15 And what do you base that on?</p> <p>16 A. Just that I've not seen any 17 differences, and I'm sure I've probably 18 used both.</p> <p>19 Q. Now, is this something 20 that you've researched, the differences 21 between mechanically and laser-cut TVTs 22 and TVT-Os?</p> <p>23 A. Other than what I've read or 24 heard.</p>
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<p>1 when you do TVT or TVT-O procedures, do 2 you use laser-cut or mechanically-cut 3 mesh?</p> <p>4 A. I'm not particularly sure 5 which one it is. I imagine it's the 6 environment or the country or whatever 7 that the products were made in and 8 shipped from or shipped to.</p> <p>9 Q. Doctor, as you sit here 10 today --</p> <p>11 A. I'd say that it's not a 12 laser cut.</p> <p>13 Q. Doctor, with -- would you 14 agree with me that as you sit here 15 today, when you're performing surgery 16 in the OR, you don't know which 17 device you're being given, a laser-cut 18 TVT or TVT-O or a mechanically-cut TVT 19 or TVT-O?</p> <p>20 MS. GERSTEL: Object to the 21 form.</p> <p>22 THE WITNESS: That is 23 correct.</p> <p>24 BY MR. ORENT:</p>	<p>1 Q. And what have you read or 2 heard?</p> <p>3 A. Just that there are really 4 no major differences as far as the 5 strength.</p> <p>6 Q. Fair to say that you're not 7 an expert on any differences that may 8 exist between the two?</p> <p>9 A. I am not an expert.</p> <p>10 Q. And fair to say that if 11 there are any differences, chemical or 12 physical property differences, that you 13 haven't been provided any information 14 relative to that specific to finding -- 15 to doing this report?</p> <p>16 MS. GERSTEL: Object to the 17 form.</p> <p>18 THE WITNESS: Are you 19 referring to anything along the 20 lines of any potential little 21 particles or anything coming off 22 the -- the material?</p> <p>23 BY MR. ORENT:</p> <p>24 Q. No, no, I'm asking in terms</p>

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<p>1 of safety and efficacy profile. You've</p> <p>2 not seen any -- any --</p> <p>3 A. Any --</p> <p>4 Q. -- documents or medical</p> <p>5 studies discussing the difference between</p> <p>6 laser cut and mechanically cut, correct?</p> <p>7 A. I think it would have come</p> <p>8 out in the -- the literature if there was</p> <p>9 a major difference. There would be --</p> <p>10 the safety, efficacy, and success rates</p> <p>11 are pretty ubiquitous around the world.</p> <p>12 It's not something that's something</p> <p>13 strange and unique that one country has a</p> <p>14 terrible success rate and the other</p> <p>15 country that has laser cut has great</p> <p>16 results or just the opposite.</p> <p>17 Q. Now, Doctor, have -- did you</p> <p>18 do a literature search to look at whether</p> <p>19 or not TVT and TVT-O have been compared,</p> <p>20 the laser cut to the mechanically cut,</p> <p>21 head to head?</p> <p>22 A. I have not, other than I</p> <p>23 know that it's interspersed within</p> <p>24 different regions of the world, and --</p>	<p>1 A. It's a compilation of all</p> <p>2 their own analysis or meta-analysis of</p> <p>3 all their committees. They've looked</p> <p>4 over all the data that's out there and --</p> <p>5 and are speaking as far as what they</p> <p>6 believe is the -- is their opinion on</p> <p>7 what would be available if slings weren't</p> <p>8 available.</p> <p>9 They're talking about every</p> <p>10 bit of information that they've been able</p> <p>11 to get from SUFU, Society of Urodynamics</p> <p>12 and Female Urology, or now it's called</p> <p>13 Female Pelvic Medicine and Urogenital</p> <p>14 Reconstruction. They've expanded it</p> <p>15 because of the new fellowship training.</p> <p>16 But all these societies, all</p> <p>17 this data, and have come up with their</p> <p>18 opinions and are reinforcing them as we</p> <p>19 speak, and there isn't a single society</p> <p>20 out there that had said, Oh, don't use</p> <p>21 this. They're saying this -- the slings</p> <p>22 are the gold standard. They far outweigh</p> <p>23 any of the other procedures that are out</p> <p>24 there, and if this gets interfered with,</p>
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<p>1 but the data that's out there, it's</p> <p>2 pretty much ubiquitous throughout the</p> <p>3 world and reported even in the European</p> <p>4 societies and regulatory aspects.</p> <p>5 Like over in England, NICE,</p> <p>6 they still consider this is a gold</p> <p>7 standard procedure, as well as every</p> <p>8 single society in the -- the US, as well</p> <p>9 as the international societies,</p> <p>10 International Continence Society,</p> <p>11 International Urogyn Society [sic], NICE.</p> <p>12 It's -- the efficacy is there, the safety</p> <p>13 is there, and -- and you'd think that</p> <p>14 they would end up mentioning things like</p> <p>15 the different ways in which something was</p> <p>16 cut.</p> <p>17 Q. Now, Doctor, you just</p> <p>18 referenced AUGS. You would agree with me</p> <p>19 that the AUGS statement is not a</p> <p>20 scientific statement, correct?</p> <p>21 MS. GERSTEL: Object to the</p> <p>22 form.</p> <p>23 BY MR. ORENT:</p> <p>24 Q. It's -- it's a --</p>	<p>1 women's health will be set back decades.</p> <p>2 Q. Now, Doctor --</p> <p>3 MR. MORIARTY: It looks like</p> <p>4 you're about to launch into a long</p> <p>5 series of questions about this.</p> <p>6 MR. ORENT: Yup.</p> <p>7 MR. MORIARTY: Let's take</p> <p>8 five minutes.</p> <p>9 MR. ORENT: Sure.</p> <p>10 (Discussion off the</p> <p>11 stenographic record.)</p> <p>12 (A recess was taken from</p> <p>13 12:30 p.m. until 12:43 p.m.)</p> <p>14 (Reporter read back from the</p> <p>15 stenographic record.)</p> <p>16 BY MR. ORENT:</p> <p>17 Q. Doctor, I'm going to mark</p> <p>18 and hand you Exhibit 3 to today's</p> <p>19 deposition.</p> <p>20 - - -</p> <p>21 (AUGS Position Statement,</p> <p>22 marked for identification as</p> <p>23 Exhibit No. 3.)</p> <p>24 - - -</p>

16 (Pages 58 to 61)

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<p>1 BY MR. ORENT: 2 Q. That is the AUGS statement 3 that you were referring to, correct? 4 A. When did this come out? 5 This is the 14th. Yeah. There's 6 actually an addendum on this that is -- 7 Q. This year? 8 A. -- that I was privy to see 9 just a day or two -- 10 Q. Yes. 11 A. Coming to a neighborhood 12 near you. It's pretty extensive, as 13 well. 14 Q. The -- 15 A. Doug Hale did -- did the 16 letter. He's the president of AUGS. 17 Q. You would agree, Doctor, 18 that this is not a peer-reviewed 19 statement, correct? 20 A. It is a consensus statement 21 on review of all the literature and it's 22 done by a very reputable group that are 23 probably the most scientific-minded 24 people. There's -- AUGS members are at</p>	<p>1 a formal peer-review process, correct? 2 A. It's about as firm a peer 3 review as you could possibly get -- 4 Q. It's -- 5 A. -- by way of looking at and 6 reviewing all the papers that were peer 7 reviewed and putting them together. 8 Q. Well, a literature summary 9 piece, an academic piece that discusses 10 literature and is published goes through 11 a peer-review process just like original 12 research, correct? 13 MS. GERSTEL: Object to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. ORENT: 18 Q. And this did not go through 19 a formal peer-review process, correct? 20 A. It went through the 21 committee that makes up pretty much the 22 board that reviews most of these papers. 23 Q. No. 24 A. So yes, it is a very</p>
Page 63	Page 65
<p>1 least 1500 strong. SUFU members, because 2 this is a combined SUFU and AUGS society 3 consensus, SUFU is about 500 of the top 4 urologists in the world that are involved 5 in SUFU. 6 So, yes, it is a -- it isn't 7 a -- it is a scientific paper from the 8 standpoint of review of the literature 9 was exceedingly extensive. 10 Q. Well, this was not peer 11 reviewed, correct? 12 A. We are -- 13 MS. GERSTEL: Objection. 14 THE WITNESS: -- the peer 15 reviews -- reviewers, I should 16 say, so people -- most people that 17 are on the editorial staffs and 18 the boards throughout the world 19 belong to these societies. 20 BY MR. ORENT: 21 Q. I understand that. 22 A. They write the -- they are 23 the -- the review committees. 24 Q. But this did not go through</p>	<p>1 heavily-scrutinized document and was 2 painstakingly put through to be as 3 thorough as possible. 4 Q. Well, now, Doctor, you say 5 it went through committee. Who's on the 6 committee besides the named authors? 7 A. Who's in the committee? 8 Q. Uh-huh. 9 A. There's probably about 30 10 docs. 11 Q. Who are they? 12 A. I can't name them right off 13 the bat. 14 Q. What was the process in 15 drafting this particular statement? 16 A. The process? 17 Q. Uh-huh. 18 A. It was looking over the 19 literature, collecting and looking over, 20 say, the Seratis, Nilssons, and -- and 21 the -- the meta-analysis that was done by 22 the Cochran studies, the -- you name it, 23 it was put through and looked at to see 24 if there was anything -- any -- where --</p>

17 (Pages 62 to 65)

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<p>1 where they should lie in their opinions 2 on this. 3 Q. Did you have any personal 4 involvement in this? 5 A. I did not, other than I got 6 shown it before it got released -- 7 Q. Now, Doctor, you're aware 8 that -- 9 A. -- as a member of AUGS. 10 Q. -- this was not voted on, 11 correct? 12 A. It was not voted on. It was 13 a -- a very strong committee which 14 included the people that we had elected 15 for that position. 16 Q. This was not an ad hoc 17 group? 18 A. No, this is more of a 19 committee that we had asked to end up 20 reviewing and coming up with a statement, 21 because we, as -- as AUGS members and 22 SUFU members, which I'm a member of 23 both -- it is very concerning to us that 24 we may have to end up going back in time</p>	<p>1 hundred percent sure of how they 2 were ending up being selected into 3 there, but it was not a very -- it 4 was a very carefully selected 5 group. 6 BY MR. ORENT: 7 Q. It wasn't an informal 8 process? 9 A. It was -- if you want to 10 call it informal. It was -- they weren't 11 volunteered. 12 Q. Well, let me ask this -- 13 A. They were asked into it 14 by -- 15 Q. -- Dennis Miller was a 16 consultant for Boston Scientific; true? 17 A. He -- maybe. 18 Q. He invented the Pinnacle 19 device; true? 20 A. He did. 21 Q. Made over five million 22 dollars from Boston Scientific; true? 23 A. I have no idea. 24 Q. Howard Goldman works for</p>
Page 67	Page 69
<p>1 to doing procedures that are much more 2 aggressive, much more harmful to our 3 patients and -- and much more risky. 4 Q. Doctor, true or false, this 5 was an ad hoc committee of volunteers? 6 MS. GERSTEL: Object to 7 form. 8 THE WITNESS: It is a very 9 strongly academic committee. 10 Howard Goldstein, he's -- 11 BY MR. ORENT: 12 Q. Doctor, that wasn't my 13 question. 14 A. I'm looking at the names 15 that are listed on here. They're -- 16 Q. My question is, Doctor -- 17 A. They're a task force, yes. 18 Q. -- the individuals who 19 wrote this statement, did they volunteer 20 or were they formed on a specific 21 committee for purposes of this? 22 MS. GERSTEL: Object to the 23 form. 24 THE WITNESS: I'm not a</p>	<p>1 AMS, correct? 2 A. He's a professor at 3 Cleveland Clinic and is very reputable. 4 Q. He's consulted for AMS with 5 their mesh, correct? 6 A. I doubt it. 7 Q. Okay. Are you aware, 8 Doctor, that Dr. Goldman wrote letters to 9 the editor against Dr. Ostergard's 10 articles with Dr. Sternschuss? 11 A. I've -- 12 MS. GERSTEL: Object to the 13 form. 14 THE WITNESS: I've seen 15 them. 16 BY MR. ORENT: 17 Q. Okay. Were you aware, 18 Doctor, that AMS vetted that article and 19 Dr. Goldman worked with AMS -- 20 A. I know -- 21 Q. -- and did not disclose that 22 fact? 23 A. I know Cleveland -- 24 MS. GERSTEL: Objection.</p>

18 (Pages 66 to 69)

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<p>1 THE WITNESS: -- Clinic's 2 feeling of -- or any of the 3 Cleveland Clinic people working 4 for them is frowned upon. Let's 5 put it that way. So I don't know 6 what extent Dr. Goldman was able 7 to end up participating knowing 8 where he's from and how stringent 9 they are at it. He does -- 10 BY MR. ORENT: 11 Q. But -- 12 A. He did not make any money, 13 himself, from any kind of work that he 14 would have done for AMS, if he did do 15 anything other than consulting. 16 Q. So why did Dr. Goldman 17 vet his letter to the editor to AMS's 18 company before trying to get it 19 published? 20 MS. GERSTEL: Objection. 21 THE WITNESS: I don't know. 22 BY MR. ORENT: 23 Q. Paul Tulikangas, which 24 companies did he -- is he -- has he</p>	<p>1 literature about the safety and efficacy 2 of mesh; you'll agree with that, correct? 3 MS. GERSTEL: Objection. 4 THE WITNESS: I -- I believe 5 that you -- that's why all this is 6 coming about, and -- 7 BY MR. ORENT: 8 Q. Okay. 9 A. -- it's -- it's very 10 bothersome to a lot of us that are seeing 11 the risk factors going towards going back 12 to a procedure that if you -- if you look 13 at the sister trial, that's looking at 14 the Burch and it's looking at the 15 pubic -- pubourethral slings and a 16 comparison, they had a nearly 60-some-odd 17 percent complication rate with -- with 18 the pubovesical slings and Burches. 19 They're big incisions. They're 20 problematic. They're -- they fail -- 21 Q. I understand. I understand. 22 A. They had a 13 percent 23 success rate -- 24 Q. I understand that that's</p>
Page 71	Page 73
<p>1 consulted for that make mesh? 2 A. I can't tell you. 3 Q. Can you tell me about Eric 4 Rovner? 5 A. I can tell you that he's the 6 chairman down in -- 7 Q. MUSC, right? 8 A. -- North Carolina, Charlotte 9 -- Charleston. Charleston. 10 Q. He's at MUSC. 11 A. Oh, okay. 12 Varied procedures. He was 13 right underneath Alan Wein at Penn. 14 That's when I got to know him a lot. 15 He's president for SUFU or was and very, 16 very difficult to end up having him give 17 opinions, again, unless they're something 18 strong. He's not a big -- 19 Q. But you don't know as you 20 sit here today which mesh companies he 21 consulted for, correct? 22 A. I have no idea. 23 Q. Now, Doctor, you're aware 24 there is a debate in the scientific</p>	<p>1 your position. 2 A. -- long term. And so -- 3 Q. My question -- 4 A. -- to go back to that off of 5 one of these things is -- is like asking 6 us to go back decades in advancement for 7 women's health in particular, and it's -- 8 Q. Well, Doctor, my -- 9 A. -- very, very, very -- 10 Q. -- my question is -- 11 A. -- angering to everybody 12 that's in AUGS, SUFU. I'm also involved 13 in the international societies, IUGA. 14 Q. Well, Doctor, let me just 15 back up then. You would agree -- my 16 question is just solely this: You would 17 agree with me that there are some very 18 reputable urologists, gynecologists, and 19 urogynecologists who oppose the use of 20 transvaginal meshes? 21 A. That oppose it? 22 Q. Uh-huh. 23 A. I'm surprised at some of 24 them right now that are opposed to it,</p>

19 (Pages 70 to 73)

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<p>1 because Ostergard put in the most amount 2 of graft material and Gore-Tex because he 3 had -- 4 Q. I understand. 5 A. -- had money into -- 6 Q. No. 7 A. -- that company. 8 Q. No. My -- my question's 9 just -- 10 A. There's a lot of -- 11 Q. My question is solely: You 12 would agree that there are some very 13 well-respected, credentialed urologists, 14 gynecologists, and urogynecologists who, 15 for whatever reason, oppose the use of 16 vaginal meshes; true? 17 A. Not in the line of slings. 18 I don't know of -- maybe a couple of 19 physicians, but I don't know how 20 reputable they are at this point, because 21 if they're challenging this and they know 22 the data out there, there's a problem 23 with them. If they're on your side and 24 they're making a thousand dollars an hour</p>	<p>1 most severe incontinence. They're 2 the ISD patients. They have a 3 little bit more positioning, and 4 so there are some nuances in it. 5 BY MR. ORENT: 6 Q. I'm not asking patient to 7 patient. I'm asking the sling material, 8 itself. Is it your position that the 9 safety and efficacy of one sling that's 10 for -- designed for retropubic 11 implantation is equivalent to all 12 slings for -- 13 MS. GERSTEL: Object to the 14 form. 15 BY MR. ORENT: 16 Q. -- implantation -- 17 A. The majority of them these 18 days are Type I materials with large 19 pore, monofilamentous, polypropylene and 20 they are -- fall into that category. So 21 as far as the category, they're all in 22 that category. If there's little nuances 23 on how they're -- they're put together, 24 how they're cut, how they're done, that's</p>
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<p>1 and couple of thousand dollars for a 2 deposition, I mean, it's -- it's 3 problematic in my mind with the amount of 4 literature that's out there that's 5 supportive of midurethral slings. 6 It's -- 7 Q. There are. 8 A. It's staggering. 9 Q. There are. There is a body 10 of literature, though, and would you 11 agree not all midurethral slings are 12 created equal? 13 A. There are different slings, 14 yes. 15 Q. Some are better than others? 16 A. They're designed for 17 different purposes. 18 Q. Well, would you agree that 19 all retropubic slings are not the same? 20 MS. GERSTEL: Object to the 21 form. 22 THE WITNESS: The position 23 where they're going through is -- 24 they're fairly -- designed for the</p>	<p>1 -- that's a different realm, but these -- 2 these are fairly consistent. 3 Q. Well, when you 4 did your report, fair to say that you -- 5 your opinions on TVT and TVT-O, broadly 6 speaking, are relevant -- are designed 7 as opinions related to all midurethral 8 slings? 9 MS. GERSTEL: Object to the 10 form. 11 THE WITNESS: There's more 12 data on TVT and TVT-O than on a 13 lot of these companies other -- 14 other companies' slings. 15 BY MR. ORENT: 16 Q. Well, I guess my point is -- 17 A. There's longer data, 18 definitely. 19 Q. -- with regard to TVT-O, do 20 you have opinions on the performance of 21 TVT-O that are separate and aside from 22 TVT? Have you pulled out complication 23 rates specific to TVT-O? 24 A. I have.</p>

20 (Pages 74 to 77)

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<p>1 Q. And where are they in your</p> <p>2 report?</p> <p>3 A. I'm not sure if they're</p> <p>4 listed directly as two separate entities,</p> <p>5 but they were both considered fairly</p> <p>6 comparable. I know I put it in there or</p> <p>7 read it.</p> <p>8 Really, for the TVT-O, the</p> <p>9 only difference was a complication within</p> <p>10 the six months' period of potentially</p> <p>11 some groin pain with the TVT-O versus the</p> <p>12 retropubic approach, and there was less</p> <p>13 risks to the patients with TVT-O, and</p> <p>14 bladder perms were -- even getting into</p> <p>15 the abdominal cavity's less risky from</p> <p>16 that standpoint.</p> <p>17 Q. Doctor, would you agree that</p> <p>18 TVT and TVT-O have different risk</p> <p>19 profiles?</p> <p>20 A. They have some different</p> <p>21 risk profiles, yes.</p> <p>22 Q. Do you agree that IFUs are</p> <p>23 the same?</p> <p>24 A. I believe that they are the</p>	<p>1 A. That's the same with this.</p> <p>2 Q. First of all, you would</p> <p>3 agree, though, that the specific nerve</p> <p>4 injury related to TVT-O was not</p> <p>5 referenced in the IFU, correct?</p> <p>6 MS. GERSTEL: Objection.</p> <p>7 THE WITNESS: It's a broad</p> <p>8 paint stroke that went on with the</p> <p>9 IFU, and obviously, with the newer</p> <p>10 IFU, the litany is like this.</p> <p>11 Why? Because of all the</p> <p>12 litigation, it's pushed them</p> <p>13 towards listing everything under</p> <p>14 the sun into them. And so it</p> <p>15 should be -- the IFU should be</p> <p>16 looking at just general aspects</p> <p>17 and writing out something that's</p> <p>18 not designed to be like everything</p> <p>19 that could possibly happen.</p> <p>20 BY MR. ORENT:</p> <p>21 Q. Well, urologists typically</p> <p>22 don't operate in the obturator space, do</p> <p>23 they?</p> <p>24 MS. GERSTEL: Objection.</p>
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<p>1 same, yes.</p> <p>2 Q. And the TVT-O IFU does not</p> <p>3 call out the specific potential</p> <p>4 complication of groin pain, correct?</p> <p>5 A. It's pretty familiar from</p> <p>6 any doc wherever these things are going</p> <p>7 to --</p> <p>8 Q. That wasn't my question,</p> <p>9 Doctor.</p> <p>10 A. Whenever you're doing any</p> <p>11 kind of surgery, it's going to affect the</p> <p>12 area that it goes through. So one goes</p> <p>13 through suprapubically and one goes</p> <p>14 through the groin. If you've got a</p> <p>15 different surgical field that you're</p> <p>16 going through, it's going to have that</p> <p>17 extended normal complicating aspect, just</p> <p>18 like if you did a paravaginal defect</p> <p>19 repair, you're going to be going out into</p> <p>20 that obturator area and reattaching</p> <p>21 things. There's a risk of pain that's</p> <p>22 going to be associated with those muscles</p> <p>23 out there.</p> <p>24 Q. Well, you -- you --</p>	<p>1 THE WITNESS: They -- if</p> <p>2 they're dealing with any kind of</p> <p>3 incontinence, prolapse, or</p> <p>4 anything, yes, they -- they --</p> <p>5 BY MR. ORENT:</p> <p>6 Q. Not before the TVT-O, did</p> <p>7 they?</p> <p>8 A. Burch.</p> <p>9 Q. Going back historically,</p> <p>10 they did not operate in --</p> <p>11 A. Burch, MMK.</p> <p>12 Q. -- they didn't operate in</p> <p>13 the transobturator space, did they?</p> <p>14 A. They were out there. Any</p> <p>15 hernia repairs, that's all out towards</p> <p>16 the obturator side of things. They're --</p> <p>17 they darn well better know anatomy</p> <p>18 anyway --</p> <p>19 Q. That wasn't my question.</p> <p>20 A. -- all around the bladder.</p> <p>21 Q. My question to you is very</p> <p>22 simply: Urologists, are they used to</p> <p>23 operating in the obturator space</p> <p>24 where the TVT-O goes prior to</p>

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<p>1 this?</p> <p>2 A. It's -- it's -- everybody</p> <p>3 that is a surgeon understands the spaces</p> <p>4 that --</p> <p>5 Q. That's not my --</p> <p>6 A. -- the anatomical spaces</p> <p>7 that they're going through.</p> <p>8 Q. -- not my question.</p> <p>9 Urologists --</p> <p>10 A. Yes.</p> <p>11 Q. -- before TVT-O --</p> <p>12 A. They're surgeons.</p> <p>13 Q. -- historically --</p> <p>14 A. They're surgeons.</p> <p>15 Q. -- did they operate in the</p> <p>16 transobturator space?</p> <p>17 A. They've been in there.</p> <p>18 Q. That's your opinion?</p> <p>19 A. Yes.</p> <p>20 Q. To a reasonable degree of</p> <p>21 medical certainty --</p> <p>22 A. Yes.</p> <p>23 Q. -- gynecologists --</p> <p>24 A. Gynecologists --</p>	<p>1 should know the anatomy in those</p> <p>2 spaces.</p> <p>3 BY MR. ORENT:</p> <p>4 Q. Now, Doctor, you would agree</p> <p>5 with me that the risk profile is</p> <p>6 different between the TOT and a TVT-O?</p> <p>7 A. I'm sorry, repeat it again.</p> <p>8 I was still back --</p> <p>9 Q. Would you agree with me that</p> <p>10 between a transobturator tape and the</p> <p>11 TVT-O, and in specific Ethicon, that</p> <p>12 there's a different risk profile,</p> <p>13 outside-in versus inside-out?</p> <p>14 A. They're very similar.</p> <p>15 Q. There's a different risk</p> <p>16 profile, complication rate, isn't there?</p> <p>17 A. Minimal differences.</p> <p>18 Q. Okay. It's a lot greater</p> <p>19 blind space going with the TVT-O</p> <p>20 approach, isn't there?</p> <p>21 A. It all depends upon whether</p> <p>22 you've followed the guidelines of using</p> <p>23 the -- the little guide that goes in or</p> <p>24 whether you've decided to drop what</p>
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<p>1 Q. -- traditionally did they</p> <p>2 operate in the transobturator</p> <p>3 space?</p> <p>4 A. They probably didn't maybe</p> <p>5 know as much about it. They just said,</p> <p>6 Oh, we put some of this stuff to that</p> <p>7 stuff, but they were in the space.</p> <p>8 Whether they knew it or not is</p> <p>9 frustrating to me because I've taught a</p> <p>10 lot of them --</p> <p>11 Q. And --</p> <p>12 A. -- and they're in there, and</p> <p>13 they were all around it.</p> <p>14 Q. And you don't think Ethicon</p> <p>15 should have warned them in a space that</p> <p>16 they weren't typically working in of the</p> <p>17 specific risk of nerve injury related to</p> <p>18 transobturator meshes?</p> <p>19 A. I think they've --</p> <p>20 MS. GERSTEL: Objection.</p> <p>21 THE WITNESS: -- been</p> <p>22 educated long enough. They've</p> <p>23 gone through anatomy. They know</p> <p>24 it. They're a surgeon. They</p>	<p>1 they've given you to help with the</p> <p>2 placement of it. And there are surgeons</p> <p>3 that are -- I'd allow operating on you</p> <p>4 and surgeons that would allow to operate</p> <p>5 on my -- my significant family, and other</p> <p>6 ones that have deviation from the</p> <p>7 abilities.</p> <p>8 Q. But I --</p> <p>9 A. Unfortunately, not everybody</p> <p>10 is created equal as surgeons. There's</p> <p>11 knowledge, though, that everybody should</p> <p>12 have. When you graduate from school,</p> <p>13 you've gone through anatomy. You've had</p> <p>14 to pass the boards to know the anatomy in</p> <p>15 all those spaces. There's no excuse for</p> <p>16 you to not to, as a surgeon, whether</p> <p>17 you're a urologist, gynecologist,</p> <p>18 colorectal surgeon, not to know that</p> <p>19 space.</p> <p>20 Q. The TVT-O was designed for</p> <p>21 ease of use, correct?</p> <p>22 MS. GERSTEL: Object to the</p> <p>23 form.</p> <p>24 THE WITNESS: It was</p>

22 (Pages 82 to 85)

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<p>1 designed to avoid the retropubic 2 space which potentially -- while 3 it had -- houses the bladder and 4 potentially could house bowel in 5 it, so it was to decrease the 6 risks of any complications within 7 that space. So -- and it was seen 8 that the efficacy of it was 9 equivalent for those patients in 10 particular that did not have 11 intrinsic sphincter deficiency -- 12 BY MR. ORENT: 13 Q. And in -- 14 A. -- on urodynamics. 15 Q. In terms of groin and thigh 16 pain, avoiding injury from the TVT-O 17 device, how does it compare in the 18 literature between the outside-in and 19 inside-out approaches? 20 A. It's fairly comparable, 21 maybe slightly higher, but there's other 22 groin pain that comes from the 23 outside-in -- 24 Q. Would you agree, Doctor --</p>	<p>1 BY MR. ORENT: 2 Q. And where in your report is 3 that cited? 4 A. I probably -- it was a 5 shortened period of time. I didn't 6 probably put it in, and I probably could 7 have. 8 Q. And would you agree with me, 9 Doctor, that the erosion rates are 10 different between TVT and TVT-O? I 11 should say urethral erosion rates. 12 A. There is a minor increase. 13 Q. And by percentage points 14 what is that? 15 A. One or two percentage 16 points. 17 Q. And in some studies there's 18 actually a doubling; is that right? 19 A. Depends upon -- I mean, it's 20 rare to begin with, and so rare going to 21 -- from .01 to .02 being a doubling, I 22 guess you could say that it's right, 23 but -- 24 Q. Well, Doctor, did you --</p>
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<p>1 A. -- and a bigger dissection 2 that you have to make for the outside-in, 3 which leads to other complications of the 4 procedure, which is that you're cutting 5 some of the nerves around the urethra, 6 which leads to a higher risk of intrinsic 7 sphincter deficiency afterwards. It's -- 8 Q. Doctor, would you agree with 9 me that -- well, strike that. 10 Did you perform a 11 comprehensive literature review to 12 compare the TOT performance to the 13 TVT-O -- 14 MS. GERSTEL: Object to the 15 form. 16 BY MR. ORENT: 17 Q. -- inside-out versus 18 outside-in? 19 A. I've looked at that -- 20 MS. GERSTEL: Object to the 21 form. 22 THE WITNESS: -- in many 23 years, multiple times over the 24 years.</p>	<p>1 A. -- or up to 1 to 2. 2 Q. -- did you do a 3 comprehensive literature review comparing 4 TVT to TVT-O in terms of urethral erosion 5 rates? 6 MS. GERSTEL: Objection; 7 asked and answered. 8 THE WITNESS: I've -- I've 9 looked at the two differences. 10 Obviously, that's why you have -- 11 TVT-O has been decreasing some of 12 the -- the risk factors that you 13 can experience with the retropubic 14 approach; however, you need to pay 15 attention more to the patient's 16 diagnosis and you need to really 17 pay attention to their urodynamic 18 data, because there is a falling 19 off of the success rate for an 20 intrinsic sphincter deficiency 21 patient if you're doing an 22 obturator versus a retropubic 23 approach. 24 BY MR. ORENT:</p>

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<p>1 Q. And that's not in the IFU, 2 correct? 3 A. There is -- it is not 4 necessarily spoken, and it's not 5 something that they would have known even 6 at the beginning of -- of these things. 7 There -- and I have used a generalized 8 look at things, at least when I've 9 written it for myself and the products 10 and -- and my company. 11 You -- you're not going to 12 be able to mention everything out there. 13 You got to count on doctors to actually 14 have some brain about them and also to 15 have to follow the literature, because it 16 can change from month to month, year to 17 year, and you're having to end up 18 adjusting it. 19 Doesn't mean that you have 20 to change the IFU. It's a major, major 21 process to end up having to change an 22 IFU. It's just a guideline to keep -- 23 keep -- for the major use, not all the 24 little details.</p>	<p>1 A. I've consulted for many 2 companies, yes. 3 Q. What other mesh 4 manufacturers have you consulted for? 5 A. Boston Sci, Coloplast. 6 Mostly just being asked to -- to -- on a 7 consultant basis to look over a product 8 that they have or something that they 9 wanted to do. Remeex. I don't know what 10 the name of the company is. That's 11 another sling product with an adjustable 12 sling. They ask me my opinions and I'll 13 give it to them, and -- 14 BY MR. ORENT: 15 Q. And over the years, how 16 much money have you made consulting for 17 mesh companies? 18 MS. GERSTEL: Object to 19 form. 20 THE WITNESS: I really 21 couldn't tell you, but it's not 22 been huge. 23 BY MR. ORENT: 24 Q. In the six figures?</p>
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<p>1 Q. Now, Doctor, with regard to 2 yourself and your practice, you're -- 3 would you say that you're an advocate for 4 use of mesh? 5 MS. GERSTEL: Object to the 6 form. 7 THE WITNESS: Am I an 8 advocate? In the right 9 circumstances, absolutely. 10 BY MR. ORENT: 11 Q. And Doctor, you left your 12 prior practice in September, correct? 13 A. It was weaning down, and I 14 finally closed, closed it all by -- by 15 December. 16 Q. You announced the retirement 17 in September, correct? 18 A. Yes. 19 Q. And was that before you were 20 retained by Ethicon in this case? 21 A. It was before. 22 Q. And between -- over the 23 years, you've consulted for AMS and 24 Ethicon, correct?</p>	<p>1 A. Probably a little under. 2 Q. Now, Doctor, you've always 3 been a pro-mesh guy, correct? 4 A. I have been a -- a 5 pro-patient side, and I've grown -- I've 6 been able to experience from going from 7 my program where prolapse surgery was 8 considered a success if everything was 9 held inside. It didn't matter whether 10 the patient peed on themselves, defecated 11 on themselves, or had pain or had no 12 vagina left. It was successful long as 13 the doc looked at it and went, Ah, it's 14 cured. 15 Very frustrating to me. I 16 finished off my residency program, worked 17 with Cullen Richardson on the anatomy 18 just because I -- I felt like there was 19 something different. And so myself, Al 20 Bent, Rogers, there was a litany of 21 high-end physicians. We got together, 22 whoever had a cadaver, and we'd fly in, 23 we'd look over the anatomy. And Cullen 24 was a big firm believer that there</p>

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<p>1 were -- it was not stretched in 2 attenuated tissue, it was tears and 3 specific breaks in the endopelvic fascia 4 creating hernias within the pelvic floor. 5 So with that information, we 6 set out to look for ways of doing this. 7 So we were putting together things using 8 just those site specific, need of 9 tissues. It gets frustrating when you 10 start -- when you think you did the most 11 incredible job and the person falls 12 apart. 13 Q. You've been using mesh and 14 have been a proponent of it since 1998, 15 correct, or earlier? 16 A. Earlier. 17 Q. Okay. And going back to the 18 AUGS statement, you'd agree with me that 19 you don't really know the true way in 20 which this position statement was 21 adopted, correct? 22 MS. GERSTEL: Object to the 23 form. 24 THE WITNESS: It was an</p>	<p>1 THE WITNESS: -- that it was 2 a single author. 3 BY MR. ORENT: 4 Q. The initial draft -- 5 A. There -- there are some 6 letters that -- forthcoming afterwards 7 from the president of AUGS that ended up 8 with the help of all the committee 9 members and whoever else he wanted to 10 share with it, and -- and I -- I know 11 several people that have gotten that 12 information, edited it, passed it back to 13 him to end up coming together with a 14 formalized document at the end. It is 15 not a one-person. It is one person 16 acting as the spokesperson -- 17 Q. I understand. 18 A. -- and that's the president. 19 Q. The first draft that was 20 sent around, that was a single 21 author, correct? 22 A. I have no idea. This is not 23 the first draft. 24 Q. Right. And we're not --</p>
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<p>1 extensive review and it was 2 definitely passed around to us 3 to -- as a society and utilized 4 our feedback into them, which was 5 extensive. 6 BY MR. ORENT: 7 Q. Well, Doctor, that -- this 8 -- do you know -- there was no vote, 9 correct? 10 A. There was a consensus within 11 the meeting. There were definitely a lot 12 of communications to them. 13 Q. So you're not disagreeing 14 with me and the information that I'm 15 aware of that says that there was no vote 16 on this, correct? You're not disagreeing 17 with that, are you? 18 A. There was no vote on it. 19 Q. Okay. And this was written 20 by a single author and then passed around 21 to some people for comment, correct? 22 A. I don't think -- 23 MS. GERSTEL: Object to 24 form.</p>	<p>1 we're not -- 2 A. And I don't know whether 3 it's a single person that wrote that. 4 Q. Okay. 5 A. It was -- 6 Q. Ultimately, it was signed 7 onto by the individuals whose names are 8 on there, correct? 9 A. It was signed on at least by 10 the presidents of each of those 11 societies, which is -- I would anticipate 12 is in here. 13 Q. Now, Doctor, what negative 14 comments and feedback did that receive 15 before it was published? 16 A. I think for the most part, 17 it was applauded. 18 Q. Did it receive some negative 19 feedback to the authors before they 20 finalized it? 21 A. I'm sure there was 22 opportunity -- if you had an opinion that 23 was a negative one, that there was plenty 24 of open forum for your ability to talk</p>

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<p>1 about it.</p> <p>2 Q. That particular statement,</p> <p>3 it doesn't list or discuss any</p> <p>4 complications related to mesh, correct?</p> <p>5 A. It just talks about some of</p> <p>6 the safety and efficacy as compared to</p> <p>7 what other morbidities are out there.</p> <p>8 Q. It doesn't discuss the</p> <p>9 complications, does it?</p> <p>10 A. It doesn't go through</p> <p>11 specifically the -- the -- the individual</p> <p>12 papers and what came to their conclusion</p> <p>13 in there.</p> <p>14 Q. And there's only between 10</p> <p>15 and 14 articles cited, correct?</p> <p>16 A. Within those articles are a</p> <p>17 compilation of multiple, multiple papers</p> <p>18 that are in -- involved in it. Other</p> <p>19 than Nilsson, I thought there -- they had</p> <p>20 that -- the Cochran 91 or some ridiculous</p> <p>21 number of peer-reviewed, randomized,</p> <p>22 controlled trials that were done that</p> <p>23 were put into that data.</p> <p>24 Q. Now, Doctor, do you know</p>	<p>1 around, and I know --</p> <p>2 Q. And you know that you</p> <p>3 received it, correct?</p> <p>4 A. I've seen it, yes.</p> <p>5 Q. You don't know who else</p> <p>6 received it, as you sit here today,</p> <p>7 correct?</p> <p>8 A. I --</p> <p>9 MS. GERSTEL: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: Well, this</p> <p>12 one, it's -- it's -- everybody's</p> <p>13 got it.</p> <p>14 BY MR. ORENT:</p> <p>15 Q. Not before it was published?</p> <p>16 A. Not before it was published.</p> <p>17 Q. Before it was published, who</p> <p>18 else received it for comment besides you?</p> <p>19 A. I'm not sure.</p> <p>20 Q. And you've been -- when we</p> <p>21 talk about letting -- openness to</p> <p>22 patients, do you tell your patients -- do</p> <p>23 you believe in being fully open and</p> <p>24 honest about the potential permanent</p>
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<p>1 whether or not only individuals who were</p> <p>2 for the use of mesh were provided a copy</p> <p>3 of this --</p> <p>4 A. No.</p> <p>5 Q. -- before it was released?</p> <p>6 A. I'm sure it was given to</p> <p>7 everybody --</p> <p>8 Q. You're sure --</p> <p>9 A. -- and at that point --</p> <p>10 Q. -- or you think?</p> <p>11 A. I'm pretty sure.</p> <p>12 Q. And what's the basis for</p> <p>13 being pretty sure?</p> <p>14 A. Just that they were -- it's</p> <p>15 a very, very, very conservative society,</p> <p>16 both of them are, and they're not about</p> <p>17 to go sticking their neck out without</p> <p>18 approaching people of high quality that</p> <p>19 they believed would give their fair</p> <p>20 feedback on it.</p> <p>21 Q. Well, again, just focusing</p> <p>22 on this particular statement, you don't</p> <p>23 have firsthand knowledge of that, do you?</p> <p>24 A. I know that it was passed</p>	<p>1 long-term complications of mesh with your</p> <p>2 patients?</p> <p>3 A. Yes.</p> <p>4 MS. GERSTEL: Object to</p> <p>5 form.</p> <p>6 BY MR. ORENT:</p> <p>7 Q. And what do you tell your</p> <p>8 patients about the controversy of mesh</p> <p>9 and the dangers of mesh?</p> <p>10 A. I was giving them the FDA</p> <p>11 form. I was giving them the AUGS and</p> <p>12 whatever forms were out there. I also --</p> <p>13 from day one, all my consent forms have</p> <p>14 everything listed in it. It's kind of</p> <p>15 scary to them because I -- I always start</p> <p>16 with death. I go death and then all the</p> <p>17 complications, infection, erosion,</p> <p>18 bleeding pain, persistent pain,</p> <p>19 dyspareunia, and -- and the --</p> <p>20 Q. And --</p> <p>21 A. -- litany goes on and on,</p> <p>22 and that's gone from probably the</p> <p>23 beginning when I left my residency</p> <p>24 program --</p>

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<p>1 Q. Well, Doctor, specific to 2 mesh. 3 A. The only anything different 4 for mesh would be erosion. 5 Q. Would you agree with me, 6 Doctor, that it's important to -- strike 7 that. 8 Doctor, did you tell your 9 client -- your patients before using mesh 10 on them that you consulted for Ethicon? 11 MS. GERSTEL: Object to the 12 form. 13 THE WITNESS: Did I? 14 BY MR. ORENT: 15 Q. Uh-huh. 16 A. Not necessarily. 17 Q. Okay. Did you tell them 18 that you consulted for AMS with regard to 19 mesh? 20 A. It's within my -- my 21 website. They have my résumé on it and 22 everything. There are times I wasn't 23 working for Ethicon; in fact, for most of 24 the -- the sling years or I should say</p>	<p>1 A. On whose complication -- 2 there was a lot of things on that. It 3 had listed everything -- 4 Q. There's a lot of things on 5 there, but there's no discussion of 6 complications. If you click on that, 7 Doctor -- 8 A. Which one was it that you 9 looked at? I had two websites. One was 10 really old, and one was, I think, the 11 Institute for Pelvic Medicine, I think it 12 is. 13 Q. What's the new one? 14 A. I'll have to get it to you. 15 My partner created it. 16 Q. Is that Dr. Babin? 17 A. Yes. It's extensive. It's 18 -- it's in three-part harmony, got to be 19 in there because the FDA statement's in 20 there. So that's -- that's got it all 21 listed out -- 22 Q. Doctor -- 23 A. -- in spades. 24 Q. -- I'm going to mark as --</p>
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<p>1 the -- the latter part when all this 2 graft was, I was more of a consultant for 3 other products for J&J, such as their 4 nerve stimulator pieces rather than their 5 graft materials. I did more for AMS in 6 there -- in those time periods. 7 Q. And you also consulted with 8 Boston Scientific and other mesh 9 companies, right? 10 A. Just mainly giving them my 11 opinions on what I was looking at, what I 12 was seeing and feeling, the tensile 13 strength, the stretchability, the -- the 14 things that you call me as not an expert 15 at the -- all those I -- I think I'm an 16 expert as far as knowing what would feel 17 good in a patient. 18 Q. And Doctor, you on your 19 website believe it's important to be 20 truthful to your patients, correct? 21 A. Absolutely. 22 Q. So, Doctor, why under mesh 23 complications is there no information 24 on your website?</p>	<p>1 MR. ORENT: What's the next 2 exhibit? 3 THE COURT REPORTER: 4. 4 BY MR. ORENT: 5 Q. -- Exhibit 4 one of the 6 pages from your website from clinical 7 research. 8 A. Uh-huh. 9 - - - 10 (Pelvic-health-surgery.com 11 Clinical Research page printout, 12 marked for identification as 13 Exhibit No. 4.) 14 - - - 15 BY MR. ORENT: 16 Q. Doctor, do you stand by 17 everything that you put on your website? 18 A. I don't monitor it. 19 Q. I've presented a particular 20 statement here, and if you would, read to 21 the jury this statement. 22 A. Just the headline? 23 Q. No, the "The FDA 24 requested..."</p>

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<p>1 A. Where?</p> <p>2 Q. If you go into the --</p> <p>3 A. Oh, down below you mean?</p> <p>4 Q. -- the body of that</p> <p>5 paragraph, yeah.</p> <p>6 A. Besides the "...chosen to</p> <p>7 participate in AMS Elevate 522K</p> <p>8 postmarket study of Vaginal Mesh</p> <p>9 Placement in Pelvic Organ Prolapse</p> <p>10 Surgery for the FDA.</p> <p>11 "The FDA requested some very</p> <p>12 specific follow-up studies on the</p> <p>13 placement of mesh via the vaginal route.</p> <p>14 Dr. Babin and Dr. McKinney are excited to</p> <p>15 have been chosen to participate --"</p> <p>16 (Reporter clarification.)</p> <p>17 THE WITNESS: "-- are</p> <p>18 excited to have been chosen to</p> <p>19 participate in these important</p> <p>20 studies. They were chosen to</p> <p>21 participate due to their</p> <p>22 experience in placing vagina mesh</p> <p>23 and the safety records as well as</p> <p>24 surgical outcomes they have</p>	<p>1 A. Yes. We were actually</p> <p>2 involved in three arms of the study:</p> <p>3 Native tissue and anterior compartment as</p> <p>4 well as posterior compartment for use of</p> <p>5 the mesh. So they were given all three</p> <p>6 options to choose from and whichever they</p> <p>7 chose -- it wasn't randomized control.</p> <p>8 It was randomized as far as the patient's</p> <p>9 choice, native tissue or not.</p> <p>10 Q. And you say, "Again, these</p> <p>11 meshes are already approved by the</p> <p>12 FDA..." Did I read that piece correctly?</p> <p>13 A. They are already approved</p> <p>14 for use in surgery.</p> <p>15 Q. These meshes weren't</p> <p>16 approved by the FDA prior to this, were</p> <p>17 they?</p> <p>18 A. 522, I guess.</p> <p>19 Q. They were 510(k). They were</p> <p>20 cleared, correct?</p> <p>21 A. 510(k). I'm --</p> <p>22 Q. And they were not approved</p> <p>23 for safety and efficacy -- proven safety</p> <p>24 and efficacy before this, were they?</p>
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<p>1 experienced over the last decade</p> <p>2 of placing vaginal mesh in their</p> <p>3 patients. Dr. Babin and Dr.</p> <p>4 McKinney believe these studies are</p> <p>5 paramount in helping resolve the</p> <p>6 controversies that currently</p> <p>7 surround this important option for</p> <p>8 women who suffer pelvic prolapse</p> <p>9 and have risk factors for failure</p> <p>10 of a surgical repair with native</p> <p>11 tissue alone. Again, these meshes</p> <p>12 are already approved by the FDA</p> <p>13 for use in surgery and many</p> <p>14 patients have undergone this exact</p> <p>15 mesh placement over the last</p> <p>16 several years. You can feel</p> <p>17 confident about participating in</p> <p>18 the study if you are a patient</p> <p>19 determined to need a mesh for your</p> <p>20 prolapse repair as it would be the</p> <p>21 same mesh that would be used if</p> <p>22 you were not in the study."</p> <p>23 Q. And Doctor, do you stand by</p> <p>24 that paragraph?</p>	<p>1 A. It was my thought process</p> <p>2 that the 510(k) would have been</p> <p>3 sufficient for use in surgery and,</p> <p>4 therefore, it was approved that way.</p> <p>5 Q. Now, Doctor, did you think</p> <p>6 your patients were -- do you think your</p> <p>7 patients had the right know that there</p> <p>8 was a difference between the two?</p> <p>9 MS. GERSTEL: Just want to</p> <p>10 put an objection on the record to</p> <p>11 the extent that we're going into</p> <p>12 transvaginal meshes at this</p> <p>13 point --</p> <p>14 MR. ORENT: Okay.</p> <p>15 MS. GERSTEL: -- and</p> <p>16 transcending beyond the --</p> <p>17 BY MR. ORENT:</p> <p>18 Q. Doctor --</p> <p>19 A. That it is -- it's almost</p> <p>20 like a -- I consider it almost like a</p> <p>21 splitting of a hair because it is --</p> <p>22 you're making it sound like these</p> <p>23 instruments that we were putting in or</p> <p>24 grafts that we were putting in were not</p>

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<p>1 approved through a normal process to be 2 able to implant into patients. These 3 were approved and they were allocated for 4 the use. 5 Q. Well, Doctor, there's a 6 material difference in what goes into a 7 510(k) and a 522; we -- than a PMA, 8 correct? We've already discussed that? 9 A. We've done that, yes. 10 Q. And so my question to you 11 is: Do -- did your patients -- did they 12 deserve to know -- do they have a right 13 to know that there is a difference 14 between 510(k) and premarket approval and 15 the processes and the amount of the data 16 that goes into a device through each 17 process before being implanted by you? 18 MS. GERSTEL: Object to 19 form. 20 THE WITNESS: Well, these 21 products have been out there for a 22 long time with a lot of -- a lot 23 of data that was on them, as well 24 as for the 510(k). It's -- the</p>	<p>1 need for premarket studies was recalled? 2 Do you think that they should have known 3 that? 4 MS. GERSTEL: Object to 5 form. 6 THE WITNESS: I think it 7 should have been up to the FDA to 8 end up not issuing the 510(k)s if 9 they knew that there was anything 10 different from that original 11 predicate device. It's not for me 12 to end up deciding on it. It's -- 13 it was -- the FDA didn't go ahead 14 and extend it all the way across. 15 BY MR. ORENT: 16 Q. Well, it's up to -- 17 A. There's so much data that 18 was out there at the time for -- 19 Q. Well, it's up to you to 20 inform your patients, right? You tell 21 your patients -- you choose what you tell 22 your patients; true? 23 A. I -- 24 MS. GERSTEL: Object to</p>
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<p>1 original predecessor for these was 2 FDA approved, and, therefore, the 3 510(k) was an extension of that 4 original FDA approval. So it's 5 kind of splitting hairs when 6 you're saying that it wasn't FDA 7 approved. It was a -- it was a 8 predicate that was off of an 9 FDA-approved material that was 10 extended through a 510(k) 11 approval. 12 BY MR. ORENT: 13 Q. What was the ultimate 14 predicate? 15 A. Oh, God. ProteGen or 16 something. I -- I can't -- I -- I can't 17 remember the original -- 18 Q. ProteGen was recalled, 19 wasn't it? 20 A. It was. 21 Q. Uh-huh. So do you think 22 that the patients that you put mesh into 23 had a right to know that the ultimate 24 predicate of the device that relieved the</p>	<p>1 form. 2 THE WITNESS: I gave them 3 what I thought was the right 4 information about the use of a -- 5 a material that has been used for 6 a long time. 7 BY MR. ORENT: 8 Q. Not in the vagina; true? 9 A. It's a hernia. The -- the 10 vaginal prolapse is a hernia. There is 11 small intestine that falls into there. 12 There is fascial tears that creates the 13 cystoceles, the rectoceles, the 14 enteroceles. They're hernias. 15 Q. You would agree that the 16 vagina's a different environment than 17 the abdomen, right? 18 A. There is skin covering over 19 the fascial defects just like abdominal 20 wall has fascial defects. It's a little 21 bit thinner material, but nonetheless, 22 there's skin that covers over -- 23 Q. Biomechanically -- 24 A. -- the --</p>

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<p style="text-align: right;">Page 114</p> <p>1 Q. -- they're different, would 2 you agree? 3 A. They come up with a lot of 4 resistance and a lot of trauma, just like 5 the abdominal wall can, from being 6 punched, being hit, doing sit-ups. It's 7 all kinds of forces that are faced on it. 8 The whole reason why we started going to 9 these were because the native tissue in 10 that area was falling apart and creating 11 recurrence of these same issues that the 12 patient suffered, quality of life 13 issues -- 14 Q. Now -- now, Doctor -- 15 A. -- tremendous -- 16 Q. -- with -- you say that this 17 exact mesh placed over the last several 18 years -- you -- this article seems to 19 indicate that Elevate has had a positive 20 experience up to that point in time. 21 Would you agree with me that there were 22 no randomized control trials on Elevate 23 at this time? 24 A. There were lot of series of</p>	<p style="text-align: right;">Page 116</p> <p>1 here? 2 A. Well, I would -- I'm saying 3 that when I was going to end up offering 4 these patients the -- a choice of using a 5 graft, which I gave them the 2012 6 statement in there from the FDA, that 7 they were aware of what the FDA was 8 looking at, and that's why the 522 was 9 being done. It was not trying to pull 10 the wool over on patients. It's -- I was 11 so transparent and very much aboveboard 12 as I thought I had been all throughout my 13 life. 14 Q. And so, Doctor, you told 15 patients that the risks outweigh the 16 benefits for the use of the Elevate 17 device? 18 MS. GERSTEL: Object to the 19 form. 20 THE WITNESS: As far as the 21 risks out -- as far as failure 22 rate, given the options, a lot of 23 these patients -- most of them 24 were recurrent of prolapse.</p>
<p style="text-align: right;">Page 115</p> <p>1 case reports and that. 2 Q. The FDA held a panel in 3 September of 2008 -- 2012, correct? 4 A. Correct. 5 Q. And the recommendation of 6 the panel was to reclassify mesh as a -- 7 for POP use as a Class III device, 8 correct? 9 A. They were moving it that 10 way, yes. 11 Q. And Elevate was one of those 12 devices that was subject to this review, 13 correct? 14 A. Yup, they all were. 15 Q. And there were a lot of 16 questions about the safety and efficacy 17 of POP mesh kits at that time, 18 correct? 19 A. There were a lot of wanting 20 to look, see at these things, yes. 21 Q. And you don't mention risk 22 factors here. You actually say, "You can 23 feel confident about participating in 24 this study," right? That's what you say</p>	<p style="text-align: right;">Page 117</p> <p>1 They've already gone through it. 2 They already know that their 3 tissue is suspect. There are -- 4 there are many reasons why they 5 would end up going down those 6 lines. 7 BY MR. ORENT: 8 Q. Did you specifically tell 9 patients that the scientific literature 10 shows that there is either no anatomic 11 benefit -- excuse me, either no quality 12 of life benefit to the mesh or no 13 anatomic benefit over traditional 14 measures and less complications? 15 MS. GERSTEL: Object to the 16 form. 17 THE WITNESS: Again, there 18 are some people that have changed 19 their data out there and success 20 rates and what they're looking at 21 with native tissue versus what's 22 going on with graft materials to 23 expand the acceptance of native 24 tissue repairs, and there's a lot</p>

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<p>1 of conflict in meetings over these</p> <p>2 changes. So it's rather</p> <p>3 frustrating to a lot of us that</p> <p>4 are out there.</p> <p>5 BY MR. ORENT:</p> <p>6 Q. So it's -- it's -- it's your</p> <p>7 -- I'm going to move on.</p> <p>8 Doctor, you've also</p> <p>9 expressed views that you think that --</p> <p>10 that all of this mesh stuff that we're</p> <p>11 hearing about is brought about by</p> <p>12 lawyers, correct?</p> <p>13 MS. GERSTEL: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: I think that</p> <p>16 there's a -- there are a number of</p> <p>17 patients that do have issues with</p> <p>18 mesh; however, there are a lot of</p> <p>19 patients that have perfectly great</p> <p>20 success rates that hear over the</p> <p>21 news and all the advertisements</p> <p>22 and everything that they should</p> <p>23 have problems and they qualify for</p> <p>24 money, and I think they go hunting</p>	<p>1 THE WITNESS: -- money as</p> <p>2 much as they get put into their</p> <p>3 head that everything and their</p> <p>4 mother can be cured if you only</p> <p>5 get rid of the mesh. I mean, I</p> <p>6 have patients come in to me with</p> <p>7 beautiful results that had rashes</p> <p>8 that got told from their</p> <p>9 dermatologist that, Unless the</p> <p>10 graft gets taken out, you're not</p> <p>11 going to get rid of your rash.</p> <p>12 They have pain in their hand, and,</p> <p>13 Oh, it's coming from the mesh in</p> <p>14 the vagina.</p> <p>15 It -- there were a lot of</p> <p>16 very harmful things that were</p> <p>17 being put into a lot of patients,</p> <p>18 and some of them have some issues</p> <p>19 anyhow in life, and they -- they</p> <p>20 put it into their heads that they</p> <p>21 were in trouble, and yet on their</p> <p>22 physical exam by independent</p> <p>23 evaluation that they did not have</p> <p>24 anything that they thought was</p>
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<p>1 for ways in which to -- or have</p> <p>2 searched out people to take out</p> <p>3 their meshes even though they did</p> <p>4 not have an issue. And it's</p> <p>5 rather -- it's rather sickening to</p> <p>6 say the least.</p> <p>7 BY MR. ORENT:</p> <p>8 Q. And Doctor, how many of your</p> <p>9 patients are gold diggers like that?</p> <p>10 MS. GERSTEL: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: There's a</p> <p>13 company out there that was --</p> <p>14 BY MR. ORENT:</p> <p>15 Q. That wasn't my question. My</p> <p>16 question is specific to you. In your own</p> <p>17 personal experience, have you ever had a</p> <p>18 patient and how many patients have come</p> <p>19 to you and told you or you have believed</p> <p>20 are solely out for money and not really</p> <p>21 suffering from mesh harm?</p> <p>22 A. I didn't say that they were</p> <p>23 looking for --</p> <p>24 MS. GERSTEL: Objection.</p>	<p>1 coming from their mesh, that it</p> <p>2 was coming from either their</p> <p>3 back -- they had sciatic nerve</p> <p>4 problems, they had abdominal</p> <p>5 incisional problems from old</p> <p>6 surgeries, they have adhesions,</p> <p>7 they have any number of things,</p> <p>8 they had shingles that came up.</p> <p>9 There --</p> <p>10 BY MR. ORENT:</p> <p>11 Q. Doctor, would you agree with</p> <p>12 me that you've explanted TVT and TVO --</p> <p>13 TVT-O products from individuals,</p> <p>14 correct?</p> <p>15 A. I have.</p> <p>16 Q. And you've seen erosions,</p> <p>17 correct?</p> <p>18 A. I have.</p> <p>19 Q. And you've seen erosions</p> <p>20 in TVT and TVT-O cases; true?</p> <p>21 A. Rare. They were more</p> <p>22 referrals to me.</p> <p>23 Q. And Doctor, you've seen</p> <p>24 groin pain as a result of TVT-O, correct?</p>

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<p>1 MS. GERSTEL: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: On one case</p> <p>4 that I wasn't able to treat</p> <p>5 conservatively --</p> <p>6 BY MR. ORENT:</p> <p>7 Q. And Doctor, how many mesh --</p> <p>8 A. -- injectable, meaning --</p> <p>9 (Reporter clarification.)</p> <p>10 THE WITNESS: I said</p> <p>11 injectable rather than surgical,</p> <p>12 injectable in the office.</p> <p>13 BY MR. ORENT:</p> <p>14 Q. Doctor, how many mesh</p> <p>15 complications have you treated?</p> <p>16 A. I -- I don't know.</p> <p>17 Q. More than a hundred?</p> <p>18 A. I have no idea. Probably</p> <p>19 within our practice.</p> <p>20 Q. More than a thousand?</p> <p>21 A. No.</p> <p>22 Q. More than 200?</p> <p>23 A. I have no -- I -- I can't</p> <p>24 even guess.</p>	<p>1 the surgery didn't work.</p> <p>2 A. Yeah, recurrence. Yes.</p> <p>3 Q. Recurrence. Well, I treat</p> <p>4 those as two separate things. But</p> <p>5 you've also had recurrence?</p> <p>6 A. Yes.</p> <p>7 Q. Point tenderness?</p> <p>8 A. Yes. It's the same kind of</p> <p>9 things that would occur with pretty much</p> <p>10 any pelvic surgery that I've done through</p> <p>11 the years.</p> <p>12 The good part about my</p> <p>13 practice is I -- probably a third of my</p> <p>14 practice is pain, and I have come up with</p> <p>15 very minimally-invasive ways of taking</p> <p>16 care of these patients, and are usually</p> <p>17 nonsurgical in etiology when you're</p> <p>18 finished with them. I do simple nerve</p> <p>19 blocks and neurolysis of the -- the --</p> <p>20 what you're calling scar tissue,</p> <p>21 injection of these trigger points, and</p> <p>22 they all go away, probably close to 80</p> <p>23 percent on one -- one treatment and one</p> <p>24 time through my office.</p>
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<p>1 Q. And Doctor, are the majority</p> <p>2 of those mesh complications that you've</p> <p>3 treated, are they from your practice or</p> <p>4 from outside of your practice?</p> <p>5 MS. GERSTEL: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: They were from</p> <p>8 outside.</p> <p>9 BY MR. ORENT:</p> <p>10 Q. And -- but you did have</p> <p>11 complications within products that you've</p> <p>12 implanted, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you've had erosion?</p> <p>15 A. Yes.</p> <p>16 Q. You've had dyspareunia?</p> <p>17 A. Yes.</p> <p>18 Q. Pelvic pain?</p> <p>19 A. Yes.</p> <p>20 Q. Failure of the device?</p> <p>21 A. What do you mean by "failure</p> <p>22 of the device"?</p> <p>23 Q. Failure of the device to</p> <p>24 treat incontinence; in other words,</p>	<p>1 Q. And Doctor, with the TVT,</p> <p>2 have you always used cystoscopy following</p> <p>3 the procedure?</p> <p>4 A. Yes.</p> <p>5 Q. That's not in the IFU,</p> <p>6 is it?</p> <p>7 A. It's just a known thing for</p> <p>8 any incontinence procedure that we look</p> <p>9 into the -- the bladder. I mean, I train</p> <p>10 all my fellows and residents that any</p> <p>11 time that you're doing any of these</p> <p>12 surgeries, like hysterectomies, that they</p> <p>13 should be putting a scope in. It's</p> <p>14 just -- in particular, if you're a</p> <p>15 procedure where you're around the</p> <p>16 bladder, you should be looking in it.</p> <p>17 Q. And Doctor, you've never</p> <p>18 been told by Ethicon that TVT can rope,</p> <p>19 correct?</p> <p>20 A. Can rope? No.</p> <p>21 Q. That it can curl?</p> <p>22 A. No.</p> <p>23 Q. That it can degrade?</p> <p>24 A. No.</p>

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<p>1 Q. That it can release 2 particles, correct? 3 A. No. 4 Q. And, in fact -- 5 A. Have I -- have I read it, 6 things about that? Yes. 7 Q. Okay. And what about 8 chronic foreign body reaction; in your 9 opinion, does mesh incite a chronic 10 permanent foreign body reaction as long 11 as the device is in there? 12 A. I don't believe it's a 13 chronic problem in every single mesh. 14 Even in your study that you looked at, 15 when you pulled it out, there were -- 16 less than 50 percent had chronic problems 17 with it. 18 Q. I guess what I'm asking 19 is not chronic problems. I'm talking 20 about the actual reaction -- 21 A. It's just an -- 22 Q. -- you know, the -- 23 A. -- inflammatory response 24 that occurs, very isolated, very close to</p>	<p>1 in any situation. 2 Q. It's permanent? 3 A. Body kind of walls it off. 4 Q. And it goes on as long as 5 the implant is in there, correct? 6 A. It's not a -- what you're 7 talking about and I -- a chronic 8 inflammatory. It's -- it's an isolated 9 area in which -- where that -- that 10 particular implant is, whether you have 11 hernia areas or you have cardiovascular 12 things, there are -- the -- the materials 13 just are quarantined off by the body, and 14 they are not progressive. 15 Q. Doctor, with regard to the 16 TVT and Ethicon -- have you ever taught 17 courses for Ethicon, proctored? 18 A. Yes. 19 Q. And did you receive money 20 for that? 21 A. Yes. 22 Q. Did you receive money for 23 teaching TVT? 24 A. Yes.</p>
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<p>1 where the mesh is. It's not a field 2 effect that affects and propagates 3 throughout the entire vagina. 4 Q. Would you agree that it's 5 chronic and permanent as long as the 6 device is in there? 7 A. It's a -- a steady state 8 that it's at. It's -- 9 Q. It's not transitory? 10 A. It's incorporated -- the -- 11 the connective tissue incorporates in. 12 You get neovascularization of these 13 grafts. It becomes the scaffold on which 14 everything is built into, very stable, 15 not chronically inflamed and like you'd 16 think of anything else in the body that 17 you had a -- an abscess or something 18 going on in there. There's not anything 19 close to that. 20 Q. But, again, it's certainly 21 not a transitory foreign body reaction, 22 correct? 23 A. It's a -- it's a reaction 24 that happens from putting any tissue in</p>	<p>1 Q. Did you receive money for 2 receive -- for teaching TVT-O? 3 A. Yes. 4 Q. When did you begin teaching 5 TVT and TVT-O? 6 A. I can't remember, but it's 7 probably in the '99 year. 8 Q. And you did it for multiple 9 years? 10 A. I did it for a few years, 11 yes. 12 Q. Multiple? 13 A. A few years, probably two, 14 maybe three. I don't -- I'm not sure 15 exactly. 16 Q. And you would agree that TVT 17 and TVT-O, regardless of the rates and 18 regardless of whether they're defective 19 or not, they can cause permanent injury 20 to some women; there are some small -- 21 there's some universe of women, however 22 big we can debate, that are permanently 23 injured by mesh -- 24 MS. GERSTEL: Object to the</p>

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<p>1 form.</p> <p>2 BY MR. ORENT:</p> <p>3 Q. -- including TVT and TVT-O,</p> <p>4 correct?</p> <p>5 A. I think that there are any</p> <p>6 pelvic surgeries or incontinence</p> <p>7 surgeries that can end up leading to</p> <p>8 problems, including death from doing</p> <p>9 nongraft material cases, probably more</p> <p>10 from -- from Burches where they've gotten</p> <p>11 into the obturator vessels and caused --</p> <p>12 Q. Okay. That's --</p> <p>13 A. -- all kinds of --</p> <p>14 Q. That's not my question. My</p> <p>15 question's --</p> <p>16 A. I know.</p> <p>17 Q. -- just to TVT and TVT-O.</p> <p>18 Would you agree that there are patients</p> <p>19 out there who are permanently injured</p> <p>20 by these devices?</p> <p>21 A. I think there -- there are</p> <p>22 patients that have been affected by a</p> <p>23 surgical procedure for incontinence,</p> <p>24 which happened to be TVT or TVT-O.</p>	<p>1 EXAMINATION</p> <p>2 - - -</p> <p>3 BY MS. GERSTEL:</p> <p>4 Q. Dr. McKinney, my name is</p> <p>5 Diana Gerstel, and I'm from the Riker</p> <p>6 Danzig firm, and we represent Johnson &</p> <p>7 Johnson and Ethicon in the pelvic mesh</p> <p>8 litigation.</p> <p>9 You've been asked some</p> <p>10 questions by plaintiff's counsel, and I'm</p> <p>11 going to ask you some follow-up</p> <p>12 questions. Are you ready to proceed?</p> <p>13 A. Yes.</p> <p>14 Q. Dr. McKinney, is it your</p> <p>15 opinion that the 2015 TVT IFU adequately</p> <p>16 warns physicians of the potential risks</p> <p>17 of the device?</p> <p>18 A. Yes.</p> <p>19 Q. And is it your opinion,</p> <p>20 Dr. McKinney, that the versions of the</p> <p>21 TVT IFUs that existed before the 2015</p> <p>22 version also adequately warned surgeons</p> <p>23 of the risks of the device --</p> <p>24 A. Yes.</p>
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<p>1 Q. Okay. Do you agree that the</p> <p>2 vagina is a clean contaminated space?</p> <p>3 A. Well, it is a clean</p> <p>4 contaminated space. Hmm. That's an</p> <p>5 oxymoron if you put it that way. There's</p> <p>6 always bacteria in the vagina.</p> <p>7 MR. ORENT: And I think</p> <p>8 that's about it, Doctor. Why</p> <p>9 don't we take a break. I'm just</p> <p>10 going to go over my notes here,</p> <p>11 but I think I think we're about</p> <p>12 done.</p> <p>13 (A recess was taken from</p> <p>14 1:46 p.m. until 1:59 p.m.)</p> <p>15 - - -</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 MR. ORENT: Objection.</p> <p>2 BY MS. GERSTEL:</p> <p>3 Q. -- devices, I should say?</p> <p>4 A. Yes.</p> <p>5 Q. And what is the basis of</p> <p>6 your opinion that the IFUs adequately</p> <p>7 warned surgeons of the risks of the TVT</p> <p>8 devices?</p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: Well, the IFU</p> <p>11 is designed to basically cover the</p> <p>12 basic premise of what can happen</p> <p>13 with it and particularly the</p> <p>14 uniqueness of the -- the actual</p> <p>15 device, and the majority of things</p> <p>16 that are standard to all surgical</p> <p>17 procedures and particularly for</p> <p>18 that area should automatically be</p> <p>19 note -- known by physicians that</p> <p>20 are operating. And whether they</p> <p>21 be urologists, gynecologists,</p> <p>22 colorectal surgeons, they should</p> <p>23 all have knowledge of that -- that</p> <p>24 aspect.</p>

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<p style="text-align: right;">Page 134</p> <p>1 So having the -- what was in 2 the original IFU was sufficient 3 enough. 4 BY MS. GERSTEL: 5 Q. Does your opinion as to the 6 adequacy of the warning information in 7 the TVT IFUs -- is that based in part on 8 your experience as a surgeon? 9 A. It's definitely based on my 10 experience as a surgeon. Obviously, it's 11 extensive. I've gone through training in 12 medical school, residency, and fellowship 13 training. All throughout the time period 14 you're taught how all these surgeries 15 affect different areas, and so the IFU's 16 just in addition to your own knowledge 17 base of what a surgical procedure would 18 entail and what could potentially happen. 19 So the IFUs just cover what is peculiar 20 to that individual device. 21 Q. Is your opinion also based 22 on your experience as a faculty member of 23 a medical school and a residency program? 24 A. Yes.</p>	<p style="text-align: right;">Page 136</p> <p>1 IFU. You've got to have gone through 2 some form of formalized training or at 3 least looked at where these devices are 4 and what their uses are and where it 5 came. 6 And they come from meetings. 7 They come from doing different courses 8 where there could be hands on, either 9 cadaveric or these models for placing 10 the -- the actual devices in. They were 11 readily available for people to be 12 trained on so that they're not the first 13 time using it -- using it on a patient, 14 or at least you would have a preceptor 15 either coming in with you or to work with 16 you and guide you through, or you were 17 going into somebody's OR that was 18 knowledgeable of the device to be able to 19 ask the questions and pick their brain 20 and understand and see what was going on 21 beforehand. 22 Q. Do surgeons also learn about 23 the risks of the TVT-O devices in 24 residency and fellowship?</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. And is your opinion also 2 based on your review of medical 3 literature? 4 A. Yes. 5 Q. Who are the intended users 6 of the TVT IFUs? 7 A. The intended users are 8 the -- the surgeons involved with it, the 9 staff within the OR, and anybody else who 10 wants to end up praising themselves of 11 the -- 12 (Reporter clarification.) 13 THE WITNESS: -- who is 14 looking at the use of that device. 15 BY MR. GERSTEL: 16 Q. Is the IFU the sole source 17 of information that surgeons have as the 18 -- strike that. 19 Is the IFU the sole source 20 of information that surgeons have as to 21 the risks of the TVT devices? 22 A. There's numerous places 23 where we all get our information from. I 24 hope not everybody is just looking at the</p>	<p style="text-align: right;">Page 137</p> <p>1 A. They definitely do at this 2 point in time, obviously. Before 1998, 3 mainly over in Europe, maybe they did -- 4 or '97 I should say, but in the States it 5 was just coming about. But after '98, it 6 was definitely taught in your residency 7 program, in your fellowships, absolutely. 8 Q. Is pelvic pain a risk that 9 is associated with all stress urinary 10 incontinence surgeries? 11 MR. ORENT: Objection. 12 THE WITNESS: Pelvic pain is 13 associated with all reconstructive 14 surgeries, including incontinence 15 procedures. 16 BY MS. GERSTEL: 17 Q. Is dyspareunia also a risk 18 of all stress incontinence surgeries? 19 A. Yes. 20 Q. What are other risks that 21 are risks of the TVT devices that are 22 also risks of all other stress 23 incontinence surgeries? 24 A. Death, infection, injury to</p>

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<p style="text-align: right;">Page 138</p> <p>1 any of the surrounding structures, 2 bladder, bowel, nerves, ureters, 3 bleeding. And particularly, there can be 4 suture erosions just like there's graft 5 erosions, damage to the urethra, 6 recurrence of the incontinence or just 7 failure of the procedure, itself, can end 8 up doing it. So that's a large number of 9 the -- the risks.</p> <p>10 Q. The pelvic pain and 11 dyspareunia which are -- well, strike 12 that.</p> <p>13 Is pelvic pain also -- is 14 chronic pelvic pain also a risk of all 15 stress urinary incontinence surgeries?</p> <p>16 A. Chronic pain, yes.</p> <p>17 Q. And that would include 18 dyspareunia, chronic dyspareunia?</p> <p>19 A. It would include 20 dyspareunia. It would include in some 21 instances -- I know when we were doing 22 Burches with -- with permanent suture 23 materials that there would be even some 24 hispareunia because of the pile of</p>	<p style="text-align: right;">Page 140</p> <p>1 than the mesh that is used in the TVT 2 devices, been studied for as long a 3 period of time for the treatment of 4 stress urinary incontinence as the mesh 5 in TVT devices has been?</p> <p>6 MR. ORENT: Objection. 7 THE WITNESS: No. 8 BY MS. GERSTEL: 9 Q. Has the safety and efficacy 10 of the TV -- of TVT been studied in 11 multiple long-term studies?</p> <p>12 A. Yes. 13 Q. And has the safety and 14 efficacy of TVT-O been studied in 15 long-term studies?</p> <p>16 A. Yes. 17 Q. Is it desirable to surgeons 18 such as yourself that the TVT-A -- T -- 19 excuse me. Strike that. 20 Is it desirable to surgeons 21 such as yourself that the TVT and the 22 TVT-O have been studied in multiple 23 long-term studies? 24 A. Absolutely, yes.</p>
<p style="text-align: right;">Page 139</p> <p>1 surgical suture material that would be 2 palpated through the periurethral area.</p> <p>3 Q. What is hispareunia?</p> <p>4 A. It means pain when a 5 gentleman puts their penis into the 6 vagina.</p> <p>7 Q. Doctor, would you agree that 8 the mesh in the TVT devices is a 9 macroporous lightweight polypropylene 10 mesh?</p> <p>11 MR. ORENT: Objection. 12 THE WITNESS: Yes. 13 BY MS. GERSTEL: 14 Q. And Dr. McKinney, do you 15 agree that the TVT devices have been 16 demonstrated in the medical literature to 17 be safe and effective in women for the 18 treatment of stress urinary incontinence 19 for up to 17 years?</p> <p>20 A. Yes, Nilsson's paper in 21 particular.</p> <p>22 Q. What is your opinion as to 23 -- well, strike that. 24 Have any other meshes, other</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. And why is that? 2 MR. ORENT: Objection. 3 THE WITNESS: Why having 4 it -- the data out there? Because 5 it's very helpful in educating our 6 patients, as well as giving us 7 more of a comfort level for the 8 use of the device, especially in 9 the environment that we're in 10 right now. 11 BY MS. GERSTEL: 12 Q. Dr. McKinney, is it your 13 opinion that reliable data does not show 14 degradation or that there is a 15 clinically-significant long-term chronic 16 inflammatory effect of TVT?</p> <p>17 MR. ORENT: Objection. 18 THE WITNESS: I'm sorry. 19 Can you read it again? 20 BY MS. GERSTEL: 21 Q. Yes. Dr. McKinney, is it 22 your opinion that reliable data does not 23 show clinically-significant degradation 24 associated with the TVT devices?</p>

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<p>1 A. Yes, there isn't good, tight 2 data. So, yes, no. 3 Q. Dr. McKinney, in other 4 words, there is no reliable data showing 5 that degradation of the mesh in the TVT 6 devices occurs to any degree that has a 7 clinical impact on patients; is that 8 true? 9 MR. ORENT: Objection. 10 THE WITNESS: That there is 11 -- clinically, there is no 12 evidence that there is a breakdown 13 or degradation of the mesh 14 material or any cytotoxicity. 15 BY MS. GERSTEL: 16 Q. Is it also your opinion, 17 Dr. McKinney, that reliable data does not 18 show there is a clinically-significant 19 long-term chronic inflammatory effect of 20 TVT on patients? 21 MR. ORENT: Objection. 22 THE WITNESS: That is 23 correct. 24 BY MS. GERSTEL:</p>	<p>1 range anywhere from around 80 2 percent up to 94 percent. 3 Serati's data for ten years 4 was about -- subjective was 89, 93 5 was objective, and urodynamic cure 6 was 91. So that's a pretty 7 significant, good paper that was 8 out there. 9 BY MS. GERSTEL: 10 Q. And Dr. McKinney, what is 11 the range of mesh exposure rates that are 12 seen in -- after implantation of TVT or 13 TVT-O? 14 MR. ORENT: Objection. 15 THE WITNESS: Very low. I 16 think I put it in here somewhere. 17 1.5 percent was roughly the rate 18 for TVT and I believe it's roughly 19 the same for TVT-O. 20 BY MS. GERSTEL: 21 Q. Can most mesh exposures that 22 occur be conservatively managed? 23 A. Absolutely, yes. 24 Q. And --</p>
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<p>1 Q. Dr. McKinney, are TVT and 2 TVT-O the gold standard and the standard 3 of care for treating stress urinary 4 incontinence? 5 A. Yes. 6 MR. ORENT: Objection. I'm 7 sorry. 8 BY MS. GERSTEL: 9 Q. What is the range of overall 10 care and improvement rates for TVT? Can 11 you say what the -- well, strike that. 12 Let me ask that a better way. 13 Can you tell us what is the 14 rate of overall care and improvement of 15 SUI after implantation of TVT or TVT-O? 16 MR. ORENT: Objection. 17 THE WITNESS: Depends upon 18 which study you're looking at, but 19 if you look at the 17-year data, I 20 guess, from Nilsson, I think it 21 was like 91 percent or something 22 for objective, and subjective was 23 87 percent. But I'd say in all 24 the papers that you read, it can</p>	<p>1 MR. ORENT: Objection. 2 BY MS. GERSTEL: 3 Q. -- what does conservative 4 management mean? 5 A. As little as just being 6 applied estrogen therapy, estrogen cream 7 tube, and if there are trigger point pain 8 areas, they can end up being injected 9 with a local to break up some little scar 10 tissue that may be around it and then 11 inject it with a neurolytic. I use five 12 percent sodium hydrochloride, knocks out 13 the nerve that may be involved in it. 14 But for the most part, we 15 use just hydrodissection and a localized 16 steroid into the area to decrease the 17 inflammation from the -- the irritant and 18 it's sufficient enough to go away. 19 Physical -- physiotherapy, massage of 20 the -- the, you know, muscles and 21 conservative therapy that way. 22 Q. Dr. McKinney, can you say 23 what percentage of TVT and TVT-O 24 surgeries are associated with -- strike</p>

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<p>1 that. Let me start that over.</p> <p>2 Dr. McKinney, can you say</p> <p>3 what -- in what percentage of TVT and</p> <p>4 TVT-O surgeries is the complication of</p> <p>5 pain or dyspareunia seen?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: The -- it's</p> <p>8 minimal from the -- the actual</p> <p>9 slings. I believe it's somewhere</p> <p>10 in the 1 percent range or less.</p> <p>11 BY MS. GERSTEL:</p> <p>12 Q. Is the rate of dyspareunia</p> <p>13 and pain higher with the Burch procedure?</p> <p>14 A. I would say yes, absolutely.</p> <p>15 Q. And is it higher with</p> <p>16 autologous fascial slings?</p> <p>17 A. Absolutely.</p> <p>18 Q. And the information you're</p> <p>19 providing as to rates of complications,</p> <p>20 is that based on -- what is that based</p> <p>21 on?</p> <p>22 A. Well, if you even look at</p> <p>23 the rates just for the sister study with</p> <p>24 the Burch and the pubovaginal slings,</p>	<p>1 I'm looking at these, and it was</p> <p>2 published in New England Journal</p> <p>3 to begin with, I think there was</p> <p>4 subsequent reporting of that in</p> <p>5 long-term aspects in the Journal</p> <p>6 of Urology, as well.</p> <p>7 So it's definitely -- those</p> <p>8 procedures are very invasive.</p> <p>9 They're very risk-apparent. I've</p> <p>10 had to do a lot of takedowns of</p> <p>11 slings because -- and to do a</p> <p>12 release for retention from a --</p> <p>13 that little midurethral tape is a</p> <p>14 pretty simple procedure. You just</p> <p>15 have to cut the sling and you're</p> <p>16 pretty much done for your</p> <p>17 urethrolisis.</p> <p>18 When you have one of these</p> <p>19 major retropubic procedures that</p> <p>20 you have to do, it's a major</p> <p>21 dissection of that entire anatomy</p> <p>22 around the urethra. There's risks</p> <p>23 of perforating into the bladder,</p> <p>24 into the urethra, and it is very</p>
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<p>1 they reported upwards of -- overall</p> <p>2 adverse events were higher with the</p> <p>3 fascial sling procedure with it being 63</p> <p>4 percent of the cases done had adverse</p> <p>5 events versus 49 percent in the Burch</p> <p>6 group just between -- everything from</p> <p>7 pain to voiding dysfunction, urinary</p> <p>8 tract infections, and the success rates</p> <p>9 were definitely much poorer in that</p> <p>10 series study and declined over time,</p> <p>11 whereas TVT slings and the obturator</p> <p>12 slings did not really decrease and</p> <p>13 deteriorate in their success rates.</p> <p>14 Q. The rates of complications</p> <p>15 that you are citing from the medical</p> <p>16 literature, are those consistent with</p> <p>17 what you've seen in your own practice?</p> <p>18 MR. ORENT: Objection.</p> <p>19 THE WITNESS: They are, I</p> <p>20 think, a little bit higher than</p> <p>21 what -- even from my practice.</p> <p>22 But, obviously, that was one of</p> <p>23 these major studies that got</p> <p>24 sponsored, I think by NIH. When</p>	<p>1 difficult to keep it from</p> <p>2 re-adhering into that space.</p> <p>3 So it's -- it's not -- it's</p> <p>4 not a fun procedure. It is hours</p> <p>5 and hours and hours of whittling</p> <p>6 away at the anatomy in there and</p> <p>7 also causes you to disrupt the</p> <p>8 nerves to the urethra when you're</p> <p>9 doing so, so high probability that</p> <p>10 you're going to have a recurrent</p> <p>11 or worse incontinence situation</p> <p>12 after you've done the release</p> <p>13 versus with a sling. It's almost,</p> <p>14 I think, 90 percent of those</p> <p>15 patients that you release it are</p> <p>16 going to still be successful.</p> <p>17 BY MS. GERSTEL:</p> <p>18 Q. Dr. McKinney, have TVT and</p> <p>19 TVT-O been recognized as safe and</p> <p>20 effective by numerous medical societies?</p> <p>21 MR. ORENT: Object.</p> <p>22 THE WITNESS: Yes, just</p> <p>23 about every single reputable one</p> <p>24 in the world, including NICE,</p>

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<p>1 including IUGA, International 2 Continence Society, all the ones 3 in the US, SUFU, AUGS, American 4 College of OB/GYN, the American 5 Urology Association, the surgeons 6 -- the surgical societies. I 7 don't think there's a single one 8 that hasn't acknowledged that this 9 is the standard. 10 BY MS. GERSTEL: 11 Q. You were asked some 12 questions this morning about the 13 AUGS/SUFU position statement. I think 14 it's dated January 2014. And the -- that 15 position statement has recently been 16 updated; is that correct? 17 A. That is correct. 18 Q. And that updated AUGS/SUFU 19 statement, which I believe the date of 20 that update was June 23rd, 2016, that 21 position statement was, itself, endorsed 22 by a number of other medical societies; 23 is that correct? 24 MR. ORENT: Objection.</p>	<p>1 A. The -- I'm sorry. The -- 2 the first initials were? 3 Q. NAFC. 4 A. National Association For 5 Continence, I believe. I know the woman 6 that runs the thing or started it, 7 anyway. I don't know if she's even still 8 alive. I -- I can't remember. Sorry. 9 MR. ORENT: Just off the 10 record. 11 (Discussion off the 12 stenographic record.) 13 BY MS. GERSTEL: 14 Q. Dr. McKinney, you were asked 15 some questions about your own consent 16 process with your patients in whom you 17 implanted mesh products. When you 18 engaged in a consent discussion with your 19 patients, did you engage in a discussion 20 with them as to the risks and benefits of 21 the mesh product at issue that was 22 tailored to each patient? 23 A. Yeah, it was an extensive 24 time period that I gave them to end up</p>
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<p>1 THE WITNESS: Pretty much 2 every one that I just have 3 mentioned has endorsed that -- 4 that statement, position 5 statement. 6 BY MS. GERSTEL: 7 Q. Was it also endorsed by 8 patient advocacy groups? 9 A. Yes. 10 Q. And do you know -- 11 MR. ORENT: Objection. 12 BY MS. GERSTEL: 13 Q. -- which ones those were? 14 A. What's the -- it's the 15 urological nursing piece and it's an 16 incontinence group. Can't remember. 17 Q. Is it NAFC? 18 A. Yes. 19 Q. And WHF? 20 MR. ORENT: Objection. 21 THE WITNESS: Yes. 22 BY MS. GERSTEL: 23 Q. And do you know what those 24 stand for?</p>	<p>1 understanding the risks, complications. 2 I had pictures on the wall in which I 3 described what their defects were, what I 4 was planning on repairing, where these 5 things were going to end up going. I had 6 a box of the implantable devices that 7 were sitting there so that they could 8 have their hands on them, touch them, 9 feel them, understand what I was putting 10 in them. 11 But it was very extensive, 12 and like I always said, I always started 13 with the worst complication first; you 14 could die. Of course, I'd joke to them, 15 and I'd say, Well, but I'll -- I'll kill 16 you if you die. But it's -- pretty much 17 sets the tone for how extensive I got 18 in -- in the definition. And it was 19 always typed out at the bottom of my 20 consent forms, perhaps it was overkill, 21 everything to do with graft material, 22 erosions and pain and failures and 23 injury -- 24 (Reporter clarification.)</p>

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<p>1 THE WITNESS: -- and injury</p> <p>2 to all the surrounding structures,</p> <p>3 and I'd list a litany of</p> <p>4 everything that could potentially</p> <p>5 be in there.</p> <p>6 BY MR. GERSTEL:</p> <p>7 Q. Dr. McKinney, has any</p> <p>8 reliable data demonstrated any</p> <p>9 clinically-significant difference between</p> <p>10 outcomes with laser-cut mesh and</p> <p>11 mechanically-cut mesh?</p> <p>12 A. There have not.</p> <p>13 Q. Dr. McKinney, you were asked</p> <p>14 about Ethicon company documents. Did you</p> <p>15 read Ethicon's patient brochures for the</p> <p>16 TVT products?</p> <p>17 A. Yes.</p> <p>18 Q. And did you rely on them?</p> <p>19 A. I usually would give them</p> <p>20 out to the patients, but I didn't</p> <p>21 completely rely on them myself because I</p> <p>22 knew what was going on. But I utilized</p> <p>23 them as far as helpful to educate and</p> <p>24 understand and teach other people that I</p>	<p>1 than reading the IFU, I have had</p> <p>2 experience writing IFUs, myself, so</p> <p>3 it's -- again, it didn't impress me one</p> <p>4 way or another. It was just a -- what I</p> <p>5 thought was adequate to understand the --</p> <p>6 the actual TVT or TVT-O when I read them.</p> <p>7 Q. Are you experienced as a --</p> <p>8 as a -- strike that.</p> <p>9 Have you as a surgeon read</p> <p>10 the IFUs for a number of different</p> <p>11 medical devices?</p> <p>12 MR. ORENT: Objection.</p> <p>13 THE WITNESS: Yes. I've</p> <p>14 read them for pretty much the --</p> <p>15 the Bard products, the Boston Sci</p> <p>16 products through the years, pretty</p> <p>17 much, probably hundreds of them.</p> <p>18 BY MS. GERSTEL:</p> <p>19 Q. And you alluded to this</p> <p>20 earlier, but I believe you testified that</p> <p>21 you also have experience as the writer</p> <p>22 of IFUs as well; is that correct?</p> <p>23 A. I have.</p> <p>24 Q. And could you tell us about</p>
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<p>1 was teaching.</p> <p>2 Q. Dr. McKinney, were you --</p> <p>3 well, strike that.</p> <p>4 Did you read the TVT</p> <p>5 Surgeon's Resource Monograph?</p> <p>6 A. Yes.</p> <p>7 Q. And did you have a role in</p> <p>8 drafting that document?</p> <p>9 A. Yes. There was a group of</p> <p>10 us that got together, and we sat and put</p> <p>11 together what we felt were the pertinent</p> <p>12 education pieces that we learned through</p> <p>13 that time period at the beginning of when</p> <p>14 TVT and TVT-O were -- or actually, it was</p> <p>15 just TVT at that time -- were propagated</p> <p>16 so we could minimize the learning curve</p> <p>17 for anybody doing these procedure that</p> <p>18 would -- we -- we took our experience and</p> <p>19 put it in there as -- as our best way of</p> <p>20 approaching each of the sections.</p> <p>21 Q. And what's been your</p> <p>22 experience with IFUs for mesh products as</p> <p>23 a surgeon?</p> <p>24 A. From the IFU aspect, other</p>	<p>1 that, please.</p> <p>2 A. Well, for my -- for my</p> <p>3 products -- I've had to work creating the</p> <p>4 IFU for my diagnostics products for</p> <p>5 urodynamics and multiple different</p> <p>6 products. Worked with my regular --</p> <p>7 regulatory department to end up putting</p> <p>8 those together, as well as the CR</p> <p>9 reports, and obviously had some guidance</p> <p>10 from regulatory, but definitely more</p> <p>11 experience probably than the majority of</p> <p>12 my fellow surgeons out there just because</p> <p>13 of that.</p> <p>14 Q. Dr. McKinney, do you have</p> <p>15 expertise in handling and placing the</p> <p>16 mesh in the TVT devices?</p> <p>17 A. I'm sorry. Could you repeat</p> <p>18 it? My -- my stomach was making a --</p> <p>19 Q. Dr. McKinney, do you have</p> <p>20 experience in handling and placing mesh</p> <p>21 in TVT devices?</p> <p>22 A. Yes.</p> <p>23 Q. And have you followed your</p> <p>24 patients' outcomes after placement of TVT</p>

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<p>1 devices in those patients?</p> <p>2 MR. ORENT: Objection.</p> <p>3 THE WITNESS: I -- I have</p> <p>4 and my fellows have looked at the</p> <p>5 outcomes for pretty much all my</p> <p>6 pelvic floor surgeries, as well as</p> <p>7 for incontinence, and we do follow</p> <p>8 these patients on a regular basis</p> <p>9 and have questionnaires that the</p> <p>10 patients had to fill out going</p> <p>11 along with what their surgical</p> <p>12 outcomes would be.</p> <p>13 BY MS. GERSTEL:</p> <p>14 Q. As a faculty member of a</p> <p>15 medical school and residency program and,</p> <p>16 I believe, a fellowship program --</p> <p>17 A. Yes.</p> <p>18 Q. -- were you required to</p> <p>19 continually assess your and your</p> <p>20 trainees' outcomes with TVT devices?</p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: We looked at</p> <p>23 our data pretty -- pretty closely</p> <p>24 to make sure that it was in tune</p>	<p>1 incontinence surgeries from its</p> <p>2 primitive beginning, I think, with</p> <p>3 doing the Kelly plications, which</p> <p>4 had a 37 percent success rate, but</p> <p>5 at the time when I was learning,</p> <p>6 that was the standard.</p> <p>7 Needle suspensions I learned</p> <p>8 because most of the urologists</p> <p>9 were doing the Pereya or Raz, and</p> <p>10 every year I was wondering why Raz</p> <p>11 had modification of the rods, even</p> <p>12 though he had a hundred percent</p> <p>13 success rate at the one-year mark.</p> <p>14 Adoni had a 42 percent. The</p> <p>15 Burch, which was what I was</p> <p>16 taught, had about an 82 percent</p> <p>17 five-year success rate from</p> <p>18 Bergman.</p> <p>19 And this whole series of</p> <p>20 episodes, I -- I got to witness</p> <p>21 the -- and that's what I was</p> <p>22 taught as my backup was the Burch,</p> <p>23 and then the retropubic sling was</p> <p>24 like last resort where we'd end up</p>
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<p>1 with what the -- the rest of the</p> <p>2 literature was out there. We had</p> <p>3 periodically some presentations</p> <p>4 that we had to do within the</p> <p>5 department to talk about these.</p> <p>6 Any major complications</p> <p>7 ended up coming in and would be</p> <p>8 reported for an M&M, or mortality</p> <p>9 and morbidity conferences.</p> <p>10 Fortunately, not -- not too many</p> <p>11 in my lifetime have been needed to</p> <p>12 be brought out for review.</p> <p>13 BY MS. GERSTEL:</p> <p>14 Q. In addition to being</p> <p>15 knowledgeable of the medical literature</p> <p>16 on the history of stress urinary</p> <p>17 incontinence surgeries, were you</p> <p>18 personally knowledgeable of the history</p> <p>19 of the different kinds of stress urinary</p> <p>20 incontinence surgeries?</p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: Obviously, my</p> <p>23 longevity in life has enabled me</p> <p>24 to see the evolution of</p>	<p>1 either taking and harvesting</p> <p>2 rectus fascia, or we'd harvest</p> <p>3 off -- the fascia lata off the</p> <p>4 leg.</p> <p>5 I did a lot more of the</p> <p>6 harvesting off the leg in Africa</p> <p>7 for patients there for their</p> <p>8 incontinence because we were</p> <p>9 dealing with fistulas and risks of</p> <p>10 the urethra having problems. So</p> <p>11 we'd -- and if they had leakage,</p> <p>12 even if we repaired the fistula,</p> <p>13 we knew that they wouldn't be able</p> <p>14 to return to their villages unless</p> <p>15 they were continent.</p> <p>16 So at the same time as we'd</p> <p>17 repair these holes and they were</p> <p>18 at risk for if we put materials in</p> <p>19 them such as a TVT, we'd have a</p> <p>20 higher risk of erosion, and we'd</p> <p>21 use autologous material in those</p> <p>22 cases.</p> <p>23 So I've had a lot of</p> <p>24 experience with use of those</p>

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<p>1 autologous side of things, as 2 well, and I got to see uses of 3 Mersilene from, I guess, the Mayo 4 Clinic people that taught me. I 5 had Glenn Hurt utilizing cadaveric 6 fascias for replacements and for 7 slings, and those -- the data came 8 back that they were being chewed 9 up and spit out and the failure 10 rate was too high. There was use 11 of Gore-Tex for these things, and 12 that was encapsulated and 13 problematic. 14 So, yeah, through the years 15 I saw a lot of the development of 16 all these different procedures. I 17 had treated with a laparoscopic 18 Burch utilizing a hernia mesh, 19 Prolene Soft lateral to the 20 urethra, stapled it on and up to 21 Cooper's ligament for -- it was a 22 hernia repair for the incontinence 23 procedure, and that was in the 24 early '90s, as a way in which to</p>	<p>1 was notoriously veins coming out 2 of the obturator canal and up over 3 the bone structure so whenever you 4 were retracting, you oftentimes 5 got a -- a cascade of blood coming 6 down from it. 7 So, yes, there was -- I 8 lived the transformation of 9 incontinence procedure and was 10 relieved when TVT, TVT-O, 11 retropubic slings from all 12 companies came about. 13 BY MS. GERSTEL: 14 Q. Dr. McKinney, among the 15 Ethicon documents that you reviewed, were 16 there documents pertaining to laser-cut 17 mesh -- the use of laser-cut mesh versus 18 the use of mechanically-cut mesh? 19 A. There were some documents in 20 there of the -- that there was laser cut, 21 and then there was the straight cut. So, 22 yes, I am aware of those. 23 MS. GERSTEL: That's all I 24 have.</p>
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<p>1 get more people to be able to 2 repair these laparoscopically 3 rather than throwing sutures, 4 which was really cumbersome and 5 difficult. 6 So, yes, I participated in 7 and moved that through. And then 8 the TVT came along and there was 9 no need for doing that type of a 10 procedure anymore, so it kind of 11 lost favor and found it so much 12 easier for the patient and for me 13 as a surgeon to end up doing a TVT 14 than it was to do all these major 15 invasive constructions, which you 16 could throw stitches. 17 You had so many risks there. 18 They'd pick up a ureter and tie it 19 off, you could throw stitches into 20 the bladder, you can obstruct 21 things, you can tie them too 22 tight, you can -- your retractors 23 can be right on the obturator 24 nerve, artery, and vein, and there</p>	<p>1 - - - 2 FURTHER EXAMINATION 3 - - - 4 BY MR. ORENT: 5 Q. Doctor, just some follow-up 6 questions on what counsel just asked you. 7 First of all, you're talking 8 about your -- your follow-up with 9 patients and your tracking of your data. 10 Do you remember those questions? 11 A. Yes. 12 Q. What's the lost 13 follow-up at one year for your TVT 14 patients? 15 A. Fortunately, not very high, 16 because my practice is mainly -- or at 17 that time was mainly from the local area, 18 from down the Jersey shore, over to 19 Pennsylvania area and up. So we made 20 them come back at basically six weeks, 21 three months, six months, and a year, and 22 then yearly thereafter. So it was a 23 pretty good follow-up on those patients. 24 Q. And for how many years did</p>

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<p style="text-align: right;">Page 166</p> <p>1 they have to come back yearly?</p> <p>2 A. For as long as I could</p> <p>3 possibly get them to come back.</p> <p>4 Q. So you felt for the TVT</p> <p>5 device, it was important to have them</p> <p>6 come back annually?</p> <p>7 A. I felt it was -- for any</p> <p>8 kind of reconstruction work for what I</p> <p>9 was doing with my fellows, it was</p> <p>10 important for them to see the -- the</p> <p>11 follow-up.</p> <p>12 Q. And in regard to the Ethicon</p> <p>13 TVT product, does it say in the IFU</p> <p>14 that follow-up should be done on an</p> <p>15 annual basis each and every year</p> <p>16 following implantation?</p> <p>17 A. Does not.</p> <p>18 Q. Okay. What was your</p> <p>19 partition [sic] rate after one year --</p> <p>20 between one and five years in terms of</p> <p>21 the aggregate data that you have between</p> <p>22 1998 and 2015?</p> <p>23 A. I -- you got to repeat that</p> <p>24 again, I'm sorry --</p>	<p style="text-align: right;">Page 168</p> <p>1 Q. Would you agree that the</p> <p>2 most significant drop-off was between</p> <p>3 year one and two?</p> <p>4 A. No, two and three.</p> <p>5 Q. Two and three? Okay. Would</p> <p>6 you agree that Ethicon does not suggest</p> <p>7 that follow-up be done at year -- at two</p> <p>8 years or three years on post-op in the</p> <p>9 IFU?</p> <p>10 A. Well, the -- the most part,</p> <p>11 the reason why I would have patients come</p> <p>12 back in is for my own self-edification</p> <p>13 and for the fellows' follow-up. It was</p> <p>14 not something -- I think most of these</p> <p>15 patients that dropped out had no problems</p> <p>16 and so they didn't see a reason why they</p> <p>17 needed to come in, especially when they</p> <p>18 didn't have a uterus or they're going to</p> <p>19 see their regular gynecologist.</p> <p>20 I had fellows calling me to</p> <p>21 give a questionnaire to see whether or</p> <p>22 not they had failed or not, and so --</p> <p>23 Q. Well --</p> <p>24 A. -- most of them that didn't</p>
<p style="text-align: right;">Page 167</p> <p>1 Q. Sure.</p> <p>2 A. -- what your --</p> <p>3 Q. Between --</p> <p>4 A. -- specific question is.</p> <p>5 Q. Sure. Between years 2 and</p> <p>6 whatever, 1998, you know, the entire</p> <p>7 cohort of patients that you've had,</p> <p>8 what's your participation rate from</p> <p>9 two years forward in terms of follow-up?</p> <p>10 A. My participation rate in</p> <p>11 following up and making sure that they --</p> <p>12 they came in? I told you it was -- it</p> <p>13 was high.</p> <p>14 Q. Right. But how many of</p> <p>15 those patients actually came back at year</p> <p>16 two; how many came back at year three;</p> <p>17 and what percentage drop-off between</p> <p>18 years two and three did you see?</p> <p>19 MS. GERSTEL: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: It was</p> <p>22 significant. It dropped off just</p> <p>23 from attrition.</p> <p>24 BY MR. ORENT:</p>	<p style="text-align: right;">Page 169</p> <p>1 come back actually had --</p> <p>2 Q. Okay. So over --</p> <p>3 A. -- good results.</p> <p>4 Q. Over your entire career,</p> <p>5 what is your -- what is your complication</p> <p>6 rate -- your aggregate complication rate</p> <p>7 at five years?</p> <p>8 A. For graft materials?</p> <p>9 Q. TVT and TVT-O, specifically</p> <p>10 those branded products.</p> <p>11 A. Okay. For anybody that had</p> <p>12 to go back to the OR was probably less</p> <p>13 than 1 percent.</p> <p>14 Q. I'm not asking probably.</p> <p>15 I'm asking to a -- to an actual number,</p> <p>16 what is the aggregate complication rate</p> <p>17 for each -- for all of the complications</p> <p>18 with TVT at five years. Not just</p> <p>19 recurrence -- excuse me, not just</p> <p>20 reoperation, but your complication rate.</p> <p>21 A. Less than 2 percent.</p> <p>22 Q. And what is that based on?</p> <p>23 A. It's based on an aggregate</p> <p>24 of who I had to bring back to the OR, any</p>

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<p>1 pain that was there, any kind of exposure 2 of graft materials. 3 Q. And how many patients fall 4 into this study? 5 A. Again, this is non -- 6 non-reported materials. It wasn't peer 7 reviewed or anything, but it's just what 8 we ended up looking at to -- 9 Q. Right. Well, what I want to 10 try and understand is if you're going to 11 testify to data -- 12 A. Yeah. 13 Q. -- and tell the jury 14 2 percent, I'm entitled to know the 15 basis of that 2 percent complication 16 rate. So what I want to know is how many 17 patients 2 percent equals. 18 I want know when those 19 patients experienced complications, 20 whether they were most common within one 21 year, between years one and five. I want 22 to know what the follow-up is after five 23 years. All of the types of things that 24 would be reported in peer-reviewed data I</p>	<p>1 shown, but the unique risks of a device 2 should be known -- should be stated in 3 the IFU; is that right? 4 A. Yes. 5 Q. And would you agree with me 6 that when TVT was launched in 1998, the 7 vast majority of doctors between 1998 and 8 2007 that were using TVT hadn't had a lot 9 of experience using other graft -- 10 artificial synthetic graft materials 11 prior to TVT? 12 MS. GERSTEL: Object to the 13 form. 14 THE WITNESS: That's kind of 15 up in the air, but -- because 16 there were a lot of graft 17 materials being used, pledgets. 18 There were all kinds of things by 19 urologists being used that were -- 20 BY MR. ORENT: 21 Q. Would you agree that TVT 22 sort of opened the floodgates to 23 polypropylene mesh as -- utilized as a 24 tape midurethral sling with the Integral</p>
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<p>1 want to know. 2 And so as you sit here 3 today, are you prepared to answer those 4 questions in that kind of detail? 5 MS. GERSTEL: Object to the 6 form. 7 THE WITNESS: I'm probably 8 more inclined to go from the 9 literature side that was peer 10 reviewed than to come off of that 11 data, even though I -- I was 12 pretty proud of the fact that I 13 did follow those patients. 14 BY MR. ORENT: 15 Q. I understand that. 16 A. Uh-huh. 17 Q. Now, you also were asked 18 some questions about the IFU, correct? 19 A. Yes. 20 Q. And you mentioned something. 21 You mentioned, actually, a couple of 22 things. You mentioned that the basic 23 premise was that in an IFU, it's your 24 opinion that not all risks should be</p>	<p>1 Theory for this treatment of stress 2 urinary incontinence? 3 A. Yes. 4 MS. GERSTEL: Object to the 5 form. 6 BY MR. ORENT: 7 Q. And that doctors previously 8 hadn't used a midurethral sling in the 9 way that TVT had been used originally in 10 2008 in the United States? 11 A. Yeah, it was a different -- 12 MS. GERSTEL: Object to the 13 form. 14 THE WITNESS: -- philosophy 15 from the use of slings in the 16 past. We're more towards the 17 support of the urethra/vesical 18 junction rather than the 19 midurethra, although Tanagho 20 believed that the mid -- his 21 modification of the Burch was a 22 midurethral stitch there. He 23 thought that that stitch was the 24 most important because that's</p>

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<p>1 where the maximum urethral closure 2 pressure was and the most -- 3 closest to the anatomical defect 4 that he thought was there, which 5 was a tear of that pubourethral 6 ligament. 7 So that's where the 8 midurethral sling and the Integral 9 Theory and Tanagho's thoughts -- 10 thought process in the 11 incontinence procedures that 12 developed -- 13 BY MR. ORENT: 14 Q. And up till 2014, there was 15 no boarding for urogynecologists, 16 correct? 17 A. '13. 18 Q. '13, sorry, there was no 19 boarding for urogynecologists, correct? 20 A. There was not a formal 21 board. No, there was not. 22 Q. And there were -- wouldn't 23 you agree that that first generation of 24 folks using TVT were entitled to know</p>	<p>1 Q. But do you think that it 2 should be truthful and reliable when 3 it's out there? 4 A. I think that it -- 5 MS. GERSTEL: Object to the 6 form. 7 THE WITNESS: -- should be a 8 useful piece of information to end 9 up reading through and 10 understanding how to use the 11 device and what the -- the side -- 12 sideline activity or misadventures 13 could be. 14 BY MR. ORENT: 15 Q. And so you would agree that 16 when material is in an IFU, which would 17 be -- in terms of contraindications, a 18 doctor should be able to rely upon that? 19 A. They should be able to read 20 it and understand a general concept of 21 what can potentially happen. 22 Q. And should a doctor who 23 reads an IFU be able to understand the 24 warnings in the IFU?</p>
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<p>1 about the nature and severity of 2 complications with synthetics that they 3 previously hadn't been exposed to? 4 MS. GERSTEL: Object to the 5 form. 6 THE WITNESS: I don't know 7 what you're trying to drive at, 8 but it was pretty well known that 9 there were risks and complications 10 to any kind of surgical 11 intervention. Any time that 12 you're using a permanent material, 13 suture or otherwise, you had risk 14 of it showing up, and it was known 15 to most of these physicians that 16 there could be issues. 17 BY MR. ORENT: 18 Q. Do you agree that a doctor 19 should be able to rely on an IFU, once 20 it's already printed, that the doctor 21 should be able to rely upon it for 22 contraindications? 23 A. I'd say that probably only 24 about 10 percent even read the IFUs.</p>	<p>1 A. Should be able to. 2 Q. Okay. And for TVT, in fact, 3 the -- when TVT was brought over to the 4 United States, the cohort that had the 5 17-year experience was done in Europe, 6 correct? 7 A. Nilsson. 8 Q. And, in fact, the procedure 9 or the implant technique that was used on 10 those folks was actually different than 11 the implant technique used in the United 12 States, correct? 13 A. Not -- it all depends. 14 Q. Well, the -- let me ask you 15 this: The original implant technique 16 in Europe was done with the patients 17 awake, correct? 18 A. A lot of them. 19 Q. And -- 20 A. Some were even done with 21 spinal anesthesia, so that's -- 22 Q. Well, that's -- that was 23 going to be my next question. 24 A. Yeah.</p>

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<p style="text-align: right;">Page 178</p> <p>1 Q. And that was designed --</p> <p>2 A. It was a different --</p> <p>3 Q. -- for tensioning of the</p> <p>4 device, correct?</p> <p>5 A. The spinal, I had a problem</p> <p>6 with them doing it that way, but it was</p> <p>7 more for the passage of the needles to</p> <p>8 make sure that the patients were in</p> <p>9 position. It also had something to do</p> <p>10 with waking them up and having them</p> <p>11 participate, yes.</p> <p>12 Q. And that was -- important in</p> <p>13 the original study was -- the proper</p> <p>14 tensioning of the device done while the</p> <p>15 patient was awake allows the doctor to</p> <p>16 know that the doctor has left the device</p> <p>17 tension free, but also that it's</p> <p>18 preventing incontinence from occurring,</p> <p>19 correct?</p> <p>20 A. Well, if you fill the</p> <p>21 bladder over there, yes. If you did a</p> <p>22 cough stress test associated with it. We</p> <p>23 can do that in the States, even if you</p> <p>24 did use general anesthesia or a form of</p>	<p style="text-align: right;">Page 180</p> <p>1 procedure that's in the TVT IFU that was</p> <p>2 brought over into the United States?</p> <p>3 A. Not necessarily. It was --</p> <p>4 there's multiple variations of doing it.</p> <p>5 That's fielder's choice, and I've -- I've</p> <p>6 done it the way it's done over in Europe.</p> <p>7 That's a lot of way I -- in which I</p> <p>8 taught mine. But when I've got general</p> <p>9 anesthesia for other procedures and</p> <p>10 obviously trying to bring them out to</p> <p>11 make them lighter or have them gag on</p> <p>12 their tubes and -- there -- there's been</p> <p>13 so much data coming out on when you do</p> <p>14 spinal injections, whether it changes the</p> <p>15 pelvic floor. They're paralyzed, so what</p> <p>16 good is it to -- to have them cough if</p> <p>17 their pelvic floor isn't going to work</p> <p>18 anyway? So, yes, lots of -- lots of</p> <p>19 variations.</p> <p>20 MR. ORENT: All right. I</p> <p>21 have no further questions. Thank</p> <p>22 you, Doctor.</p> <p>23 (Deposition concluded at</p> <p>24 2:52 p.m.)</p>
<p style="text-align: right;">Page 179</p> <p>1 it. You can have the anesthesiologist</p> <p>2 wake them up, bring them light and --</p> <p>3 and/or have them gag on their -- their ET</p> <p>4 tube.</p> <p>5 Q. But that's not done in the</p> <p>6 United States typically, correct?</p> <p>7 A. Well --</p> <p>8 Q. It's not in the IFU?</p> <p>9 A. -- again, there -- there's a</p> <p>10 lot of slings that were done in Europe</p> <p>11 that weren't just slings. They were also</p> <p>12 concomitant surgeries and that --</p> <p>13 Q. Well, I --</p> <p>14 A. There were confounding</p> <p>15 factors that are involved in a lot of</p> <p>16 these, particularly in the US, too.</p> <p>17 Q. I understand that.</p> <p>18 MS. GERSTEL: Can I ask what</p> <p>19 our time is?</p> <p>20 (Discussion off the record.)</p> <p>21 BY MR. ORENT:</p> <p>22 Q. So, Doctor, would you</p> <p>23 disagree with me that that original</p> <p>24 procedure is different than the</p>	<p style="text-align: right;">Page 181</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I HEREBY CERTIFY that the witness,</p> <p>4 TIMOTHY B. McKINNEY, M.D., was duly sworn</p> <p>5 by me and that the deposition is a true</p> <p>6 record of the testimony given by the</p> <p>7 witness.</p> <p>8</p> <p>9 It was requested before the</p> <p>10 completion of the deposition that the</p> <p>11 witness, TIMOTHY B. McKINNEY, M.D., have</p> <p>12 the opportunity to read and sign the</p> <p>13 deposition transcript.</p> <p>14</p> <p>15</p> <p>16</p> <p>17 CONSTANCE E. PERKS, CRR, CLR, CRC, RSA</p> <p>18 Notary Public I.D. #2381708</p> <p>19 Certified Court Reporter #300XI01429</p> <p>20 Certified Realtime Systems Administrator</p> <p>21</p> <p>22 (The foregoing certification of</p> <p>23 this transcript does not apply to any</p> <p>24 reproduction of the same by any means,</p> <p>unless under the direct control and/or</p> <p>supervision of the certifying reporter.)</p> <p>Dated: July 8, 2016</p>

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<p style="text-align: right;">Page 182</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 184</p> <p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages (1 - 185) and that the</p> <p>7 same is a correct transcription of the</p> <p>8 answers given by me to the questions</p> <p>9 therein propounded, except for the</p> <p>10 corrections or changes in form or</p> <p>11 substance, if any, noted in the attached</p> <p>12 Errata Sheet.</p> <p>13</p> <p>14</p> <p>15</p> <p>16 TIMOTHY B. McKINNEY, M.D. DATE _____</p> <p>17</p> <p>18</p> <p>19 Subscribed and sworn to before me this</p> <p>20 ____ day of _____, 20 ____.</p> <p>21</p> <p>22 My commission expires: _____</p> <p>23</p> <p>24 _____</p> <p>Notary Public</p>
<p style="text-align: right;">Page 183</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>	<p style="text-align: right;">Page 185</p> <p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p>

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